

DOC Code C_CT_CER_005_05	Valid from 09.03.2020	Valid until 08.06.2025	Print date 09.04.2020
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Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
01-018	-	-	No	-	-	-	-	-

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
01-018	-	-	-	-	-	-	-

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
01-018	-	-	-	-	-	-	-

- : not applicable

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
01-020	-	-	No	-	-	-	-	-

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
01-020	-	-	-	-	-	-	-

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
01-020	-	-	-	-	-	-	-

- : not applicable

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
01-019	-	-	No	-	-	-	-	-

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
01-019	-	-	-	-	-	-	-

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
01-019	-	-	-	-	-	-	-

- : not applicable

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01-021	-	-	No	-	-	-	-	-

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
01-021	-	-	-	-	-	-	-

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
01-021	-	-	-	-	-	-	-

- : not applicable

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01-022	-	-	No	-	-	-	-	-

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
01-022	-	-	-	-	-	-	-

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
01-022	-	-	-	-	-	-	-

- : not applicable

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
01-024	01	COPPER IUP	Yes	Non-Drug Therapy	1	Implant	Unknown	Implant

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
01-024	01	Yes	Other: INTRAUTERINE	10APR2012	Yes	-	Level 4: Intrauterine contraceptives Level 3: CONTRACEPTIVES FOR TOPICAL USE Level 2: OTHER GYNECOLOGICALS Level 1: GENITO URINARY SYSTEM AND SEX HORMONES

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
01-024	01	No	-	No	-	-	CONTRACEPTION

- : not applicable

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01-023	-	-	No	-	-	-	-	-

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
01-023	-	-	-	-	-	-	-

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
01-023	-	-	-	-	-	-	-

- : not applicable

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
01-025	-	-	No	-	-	-	-	-

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
01-025	-	-	-	-	-	-	-

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
01-025	-	-	-	-	-	-	-

- : not applicable

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02-001	-	-	No	-	-	-	-	-

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-001	-	-	-	-	-	-	-

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-001	-	-	-	-	-	-	-

- : not applicable

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-002	01	THYREX	Yes	Drug Treatment / Medication	25	ug (Microgram, mcg)	Once Daily (QD)	Tablet

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-002	01	Yes	Oral	UNUNK2008	Yes	-	Level 4: Thyroid hormones Level 3: THYROID PREPARATIONS Level 2: THYROID THERAPY Level 1: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-002	01	No	-	Yes	1: BENIGN THYROID TUMOUR	-	-

- : not applicable

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-002	02	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	-	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-002	02	No	Transdermal	14NOV2018	No	14NOV2018	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-002	02	No	-	No	-	TRIAL INDICATION	-

- : not applicable

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-002	03	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	-	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-002	03	No	Transdermal	06DEC2018	No	06DEC2018	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-002	03	No	-	No	-	TRIAL INDICATION	-

- : not applicable

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-002	04	PREDNISOLON	-	Drug Treatment / Medication	25	mg	Twice Daily (BID)	Tablet

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-002	04	No	Oral	14FEB2019	No	19FEB2019	Level 4: Glucocorticoids Level 3: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN Level 2: CORTICOSTEROIDS FOR SYSTEMIC USE Level 1: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-002	04	Yes	1: NEUROPATHIA VESTIBULARIS RIGHT	No	-	-	-

- : not applicable

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02-003	01	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	Yes	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-003	01	No	Transdermal	15NOV2018	No	15NOV2018	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-003	01	No	-	No	-	TRIAL INDICATION	-

- : not applicable

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-003	02	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	-	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-003	02	Yes	Transdermal	25OCT2018	No	25OCT2018	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-003	02	No	-	No	-	TRIAL INDICATION	-

- : not applicable

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-003	03	MEXALEN	-	Drug Treatment / Medication	500	mg	Twice Daily (BID)	Tablet

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-003	03	No	Oral	13NOV/2018	No	16NOV/2018	Level 4: Anilides Level 3: OTHER ANALGESICS AND ANTIPIRETTICS Level 2: ANALGESICS Level 1: NERVOUS SYSTEM

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-003	03	Yes	1: PLANNED SHOULDER OP RIGHT ARM	No	-	-	-

- : not applicable

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-003	04	NOVALGIN	-	Drug Treatment / Medication	500	mg	Once Daily (QD)	Tablet

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-003	04	No	Oral	13NOV2018	No	16NOV2018	Level 4: Pyrazolones Level 3: OTHER ANALGESICS AND ANTIPIRYETICS Level 2: ANALGESICS Level 1: NERVOUS SYSTEM

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-003	04	Yes	1: PLANNED SHOULDER OP RIGHT ARM	No	-	-	-

- : not applicable

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-003	05	PANTOLOC	-	Drug Treatment / Medication	40	mg	Once Daily (QD)	Tablet

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-003	05	No	Oral	13NOV2018	No	16NOV2018	Level 4: Proton pump inhibitors Level 3: DRUGS FOR PEPTIC ULCER AND GASTRO- OESOPHAGEAL REFLUX DISEASE (GORD) Level 2: DRUGS FOR ACID RELATED DISORDERS Level 1: ALIMENTARY TRACT AND METABOLISM

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-003	05	Yes	1: PLANNED SHOULDER OP RIGHT ARM	No	-	-	-

- : not applicable

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-003	06	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	-	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-003	06	No	Transdermal	06DEC2018	No	06DEC2018	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-003	06	No	-	No	-	TRIAL INDICATION	-

- : not applicable

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02-004	01	EUTHYROX	Yes	Drug Treatment / Medication	50	ug (Microgram, mcg)	Once Daily (QD)	Tablet

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-004	01	Yes	Oral	UNUNK2013	Yes	-	Level 4: Thyroid hormones Level 3: THYROID PREPARATIONS Level 2: THYROID THERAPY Level 1: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-004	01	No	-	Yes	1: THYREOIDECTOMY	-	-

- : not applicable

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-004	02	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	-	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-004	02	Yes	Transdermal	25OCT2018	No	25OCT2018	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-004	02	No	-	No	-	TRIAL INDICATION	-

- : not applicable

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-004	03	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	-	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-004	03	No	Transdermal	15NOV2018	No	15NOV2018	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-004	03	No	-	No	-	TRIAL INDICATION	-

- : not applicable

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-004	04	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	-	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-004	04	No	Transdermal	06DEC2018	No	06DEC2018	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-004	04	No	-	No	-	TRIAL INDICATION	-

- : not applicable

Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-005	01	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	Yes	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-005	01	No	Transdermal	06DEC2018	No	06DEC2018	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-005	01	No	-	No	-	TRIAL INDICATION	-

- : not applicable

Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-005	02	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	-	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-005	02	No	Transdermal	19NOV2018	No	19NOV2018	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-005	02	No	-	No	-	TRIAL INDICATION	-

- : not applicable

Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-005	03	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	-	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-005	03	Yes	Transdermal	25OCT2018	No	25OCT2018	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-005	03	No	-	No	-	TRIAL INDICATION	-

- : not applicable

Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-006	01	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	Yes	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-006	01	Yes	Transdermal	08NOV2018	No	08NOV2018	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-006	01	No	-	No	-	TRIAL INDICATION	-

- : not applicable

Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-006	02	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	-	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-006	02	No	Transdermal	29NOV2018	No	29NOV2018	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-006	02	No	-	No	-	TRIAL INDICATION	-

- : not applicable

Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-006	03	PARKEMED	-	Drug Treatment / Medication	500	mg	Once Daily (QD)	Tablet

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-006	03	No	Oral	27NOV2018	No	27NOV2018	Level 4: Fenamates Level 3: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS Level 2: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS Level 1: MUSCULO-SKELETAL SYSTEM

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-006	03	Yes	1: COMMON COLD	No	-	-	-

- : not applicable

Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-006	04	ACC	-	Drug Treatment / Medication	300	mg	Once Daily (QD)	Tablet

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-006	04	No	Oral	26NOV2018	No	26NOV2018	Level 4: Mucolytics Level 3: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS Level 2: COUGH AND COLD PREPARATIONS Level 1: RESPIRATORY SYSTEM

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-006	04	Yes	1: COMMON COLD	No	-	-	-

- : not applicable

Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-007	01	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	Yes	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-007	01	Yes	Transdermal	15NOV2018	No	15NOV2018	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-007	01	No	-	No	-	TRIAL INDICATION	-

- : not applicable

Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-007	02	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	-	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-007	02	No	Transdermal	06DEC2018	No	06DEC2018	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-007	02	No	-	No	-	TRIAL INDICATION	-

- : not applicable

Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-007	03	PARKEMED	-	Drug Treatment / Medication	500	mg	Once	Tablet

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-007	03	No	Oral	05DEC2018	No	05DEC2018	Level 4: Fenamates Level 3: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS Level 2: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS Level 1: MUSCULO-SKELETAL SYSTEM

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-007	03	Yes	1: COMMON COLD	No	-	-	-

- : not applicable

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Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy Drug Treatment / Medication	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-007	04	VALACICLOVIR	-	Drug Treatment / Medication	1000	mg	Once	Tablet

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-007	04	No	Oral	06DEC2018	No	06DEC2018	Level 4: Nucleosides and nucleotides excl. reverse transcriptase inhibitors Level 3: DIRECT ACTING ANTIVIRALS Level 2: ANTIVIRALS FOR SYSTEMIC USE Level 1: ANTIINFECTIVES FOR SYSTEMIC USE

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-007	04	No	-	No	-	-	PROPHYLAXIS AGAINST HERPES SIMPLEX

- : not applicable

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Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-007	05	CIPROXIM	-	Drug Treatment / Medication	500	mg	Three Times Daily (TID)	Tablet

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-007	05	No	Oral	13DEC2018	No	21DEC2018	Level 4: Fluoroquinolones Level 3: QUINOLONE ANTIBACTERIALS Level 2: ANTIBACTERIALS FOR SYSTEMIC USE Level 1: ANTIINFECTIVES FOR SYSTEMIC USE

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-007	05	Yes	1: SINUS INFECTION	No	-	-	-

- : not applicable

Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-008	-	-	No	-	-	-	-	-

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-008	-		-	-	-	-	-

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-008	-	-	-	-	-	-	-

- : not applicable

Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-009	01	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	Yes	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-009	01	No	Transdermal	13FEB2019	No	13FEB2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-009	01	No	-	No	-	TRIAL INDICATION	-

- : not applicable

Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-009	02	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	-	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-009	02	Yes	Transdermal	23JAN2019	No	23JAN2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-009	02	No	-	No	-	TRIAL INDICATION	-

- : not applicable

Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-010	01	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	Yes	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-010	01	Yes	Transdermal	23JAN2019	No	23JAN2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-010	01	No	-	No	-	TRIAL INDICATION	-

- : not applicable

Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-010	02	BLOPRESS PLUS	-	Drug Treatment / Medication	12,5/8	mg	Once Daily (QD)	Tablet

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-010	02	Yes	Oral	UNUNK2000	Yes	-	Level 4: Angiotensin II receptor blockers (ARBs) and diuretics Level 3: Angiotensin II receptor blockers (ARBs), combinations Level 2: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM Level 1: CARDIOVASCULAR SYSTEM

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-010	02	No	-	Yes	1: HYPERTENSION	-	-

- : not applicable

Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-010	04	THROMBO ASS	-	Drug Treatment / Medication	100	mg	Once Daily (QD)	Tablet

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-010	04	Yes	Oral	UNJAN2017	Yes	-	Level 4: Platelet aggregation inhibitors excl. heparin Level 3: ANTITHROMBOTIC AGENTS Level 2: ANTITHROMBOTIC AGENTS Level 1: BLOOD AND BLOOD FORMING ORGANS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-010	04	No	-	Yes	1: AORTA CALCIFICATION	-	-

- : not applicable

Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-010	05	GASTROZOL	-	Drug Treatment / Medication	5	mg	Once Daily (QD)	Tablet

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-010	05	No	Oral	01MAR2019	Yes	-	Level 4: Proton pump inhibitors Level 3: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD) Level 2: DRUGS FOR ACID RELATED DISORDERS Level 1: ALIMENTARY TRACT AND METABOLISM

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-010	05	Yes	1: ACID REFLUX	No	-	-	-

- : not applicable

Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-010	03	CONCOR	-	Drug Treatment / Medication	12.5	mg	Once Daily (QD)	Tablet

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-010	03	Yes	Oral	UNOCT2018	Yes	-	Level 4: Beta blocking agents, selective Level 3: BETA BLOCKING AGENTS Level 2: BETA BLOCKING AGENTS Level 1: CARDIOVASCULAR SYSTEM

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-010	03	No	-	Yes	1: HYPERTENSION	-	-

- : not applicable

Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-010	06	DES Loratadine	-	Drug Treatment / Medication	5	mg	Once Daily (QD)	Tablet

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-010	06	No	Oral	01MAR2019	Yes	-	Level 4: Other antihistamines for systemic use Level 3: ANTIHISTAMINES FOR SYSTEMIC USE Level 2: ANTIHISTAMINES FOR SYSTEMIC USE Level 1: RESPIRATORY SYSTEM

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-010	06	Yes	1: BIRCH ALLERGY	No	-	-	-

- : not applicable

Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-010	07	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	-	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-010	07	No	Transdermal	07MAR2019	No	07MAR2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-010	07	No	-	No	-	TRIAL INDICATION	-

- : not applicable

Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-010	08	MENISCUS SURGERY LEFT KNEE	-	Procedure	1	Other: SURGERY	Once	Not Applicable

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-010	08	No	Not Applicable	21MAR2019	No	21MAR2019	-

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-010	08	Yes	1: MENISCUS PARTIAL RUPTURE LEFT KNEE	No	-	-	-

- : not applicable

Listing 11: Prior and concomitant therapy

Part 67 of 182

Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-011	01	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	Yes	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-011	01	Yes	Transdermal	24JAN2019	No	24JAN2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-011	01	No	-	No	-	TRIAL INDICATION	-

- : not applicable

Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy Drug Treatment / Medication	Dose amount/ strength	Dose unit mg	Dosing frequency per interval	Dosage form
02-011	02	YASMIN	-		0.03 /3		Once Daily (QD)	Tablet

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-011	02	Yes	Oral	UNUNK1998	Yes	-	Level 4: Progestogens and estrogens, fixed combinations Level 3: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE Level 2: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM Level 1: GENITO URINARY SYSTEM AND SEX HORMONES

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-011	02	No	-	No	-	-	CONTRACEPTION

- : not applicable

Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-011	03	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	-	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-011	03	No	Transdermal	07MAR2019	No	07MAR2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-011	03	No	-	No	-	TRIAL INDICATION	-

- : not applicable

Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-012	01	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	Yes	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-012	01	Yes	Transdermal	24JAN2019	No	24JAN2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-012	01	No	-	No	-	TRIAL INDICATION	-

- : not applicable

Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-012	02	THYREX	-	Drug Treatment / Medication	100	ug (Microgram, mcg)	Every other day (QOD)	Tablet

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-012	02	Yes	Oral	UNUNK2008	Yes	-	Level 4: Thyroid hormones Level 3: THYROID PREPARATIONS Level 2: THYROID THERAPY Level 1: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-012	02	No	-	Yes	1: THYROID REMOVAL	-	-

- : not applicable

Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-011	04	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	-	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-011	04	No	Transdermal	14FEB2019	No	14FEB2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-011	04	No	-	No	-	TRIAL INDICATION	-

- : not applicable

Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-012	03	THYREX	-	Drug Treatment / Medication	50	ug (Microgram, mcg)	Every other day (QOD)	Tablet

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-012	03	Yes	Oral	UNUNK2008	Yes	-	Level 4: Thyroid hormones Level 3: THYROID PREPARATIONS Level 2: THYROID THERAPY Level 1: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-012	03	No	-	Yes	1: THYROID REMOVAL	-	-

- : not applicable

Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-012	04	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	-	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-012	04	No	Transdermal	13FEB2019	No	13FEB2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-012	04	No	-	No	-	TRIAL INDICATION	-

- : not applicable

Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-013	01	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	Yes	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-013	01	Yes	Transdermal	24JAN2019	No	24JAN2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-013	01	No	-	No	-	TRIAL INDICATION	-

- : not applicable

Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-013	02	BISOPROLOL	-	Drug Treatment / Medication	5	mg	Once Daily (QD)	Tablet

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-013	02	Yes	Oral	UNUNK2008	Yes	-	Level 4: Beta blocking agents, selective Level 3: BETA BLOCKING AGENTS Level 2: BETA BLOCKING AGENTS Level 1: CARDIOVASCULAR SYSTEM

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-013	02	No	-	Yes	1: HYPERTENSION	-	-

- : not applicable

Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-013	04	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	-	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-013	04	No	Transdermal	13FEB2019	No	13FEB2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-013	04	No	-	No	-	TRIAL INDICATION	-

- : not applicable

Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-013	03	TAMOXIFEN	-	Drug Treatment / Medication	20	mg	Once Daily (QD)	Tablet

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-013	03	Yes	Oral	UNAPR2015	Yes	-	Level 4: Anti-estrogens Level 3: HORMONE ANTAGONISTS AND RELATED AGENTS Level 2: ENDOCRINE THERAPY Level 1: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-013	03	No	-	Yes	1: MAMMA CARCINOMA REMOVAL	-	-

- : not applicable

Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-013	05	AMOXI-CLAVULAN	-	Drug Treatment / Medication	875/125	mg	Twice Daily (BID)	Tablet

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-013	05	No	Oral	19MAR2019	No	27MAR2019	Level 4: Combinations of penicillins, incl. beta-lactamase inhibitors Level 3: BETA-LACTAM ANTIBACTERIALS, PENICILLINS Level 2: ANTIBACTERIALS FOR SYSTEMIC USE Level 1: ANTIINFECTIVES FOR SYSTEMIC USE

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-013	05	Yes	1: SINUSITIS	No	-	-	-

- : not applicable

Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-014	01	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	Yes	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-014	01	Yes	Transdermal	24JAN2019	No	24JAN2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-014	01	No	-	No	-	TRIAL INDICATION	-

- : not applicable

Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-014	02	ANGELIQ	-	Drug Treatment / Medication	1/ 2	mg	Once Daily (QD)	Tablet

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-014	02	Yes	Oral	UNMAR2018	Yes	-	Level 4: Progestogens and estrogens, fixed combinations Level 3: PROGESTOGENS AND ESTROGENS IN COMBINATION Level 2: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM Level 1: GENITO URINARY SYSTEM AND SEX HORMONES

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-014	02	No	-	Yes	1: MENOPAUSAL SYMPTOMS	-	-

- : not applicable

Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-014	03	TRITTICO	-	Drug Treatment / Medication	150	mg	Once Daily (QD)	Tablet

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-014	03	Yes	Oral	UNAug2015	Yes	-	Level 4: Other antidepressants Level 3: ANTIDEPRESSANTS Level 2: PSYCHOANALEPTICS Level 1: NERVOUS SYSTEM

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-014	03	No	-	Yes	1: MENOPAUSAL SYMPTOMS	-	-

- : not applicable

Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-014	04	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	-	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-014	04	No	Transdermal	13FEB2019	No	13FEB2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-014	04	No	-	No	-	TRIAL INDICATION	-

- : not applicable

Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-014	05	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	-	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-014	05	No	Transdermal	07MAR2019	No	07MAR2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-014	05	No	-	No	-	TRIAL INDICATION	-

- : not applicable

Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-015	01	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	Yes	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-015	01	Yes	Transdermal	24JAN2019	No	24JAN2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-015	01	No	-	No	-	TRIAL INDICATION	-

- : not applicable

Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-015	02	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	-	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-015	02	No	Transdermal	07MAR2019	No	07MAR2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-015	02	No	-	No	-	TRIAL INDICATION	-

- : not applicable

Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-016	01	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	Yes	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-016	01	Yes	Transdermal	24JAN2019	No	24JAN2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-016	01	No	-	No	-	TRIAL INDICATION	-

- : not applicable

Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-017	01	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	Yes	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-017	01	Yes	Transdermal	24JAN2019	No	24JAN2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-017	01	No	-	No	-	TRIAL INDICATION	-

- : not applicable

Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-016	02	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	-	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-016	02	No	Transdermal	13FEB2019	No	13FEB2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-016	02	No	-	No	-	TRIAL INDICATION	-

- : not applicable

Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-018	01	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	Yes	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-018	01	Yes	Transdermal	29JAN2019	No	29JAN2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-018	01	No	-	No	-	TRIAL INDICATION	-

- : not applicable

Listing 11: Prior and concomitant therapy

Part 91 of 182

Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-018	02	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	-	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-018	02	No	Transdermal	14MAR2019	No	14MAR2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-018	02	No	-	No	-	TRIAL INDICATION	-

- : not applicable

Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-019	01	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	Yes	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-019	01	Yes	Transdermal	29JAN2019	No	29JAN2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-019	01	No	-	No	-	TRIAL INDICATION	-

- : not applicable

Listing 11: Prior and concomitant therapy

Part 93 of 182

Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-019	02	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	-	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-019	02	No	Transdermal	21FEB2019	No	21FEB2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-019	02	No	-	No	-	TRIAL INDICATION	-

- : not applicable

Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-019	03	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	-	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-019	03	No	Transdermal	14MAR2019	No	14MAR2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-019	03	No	-	No	-	TRIAL INDICATION	-

- : not applicable

Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-020	01	DESIRETTE	Yes	Drug Treatment / Medication	75	ug (Microgram, mcg)	Once Daily (QD)	Tablet

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-020	01	Yes	Oral	UNUNK2016	Yes	-	Level 4: Progestogens Level 3: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE Level 2: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM Level 1: GENITO URINARY SYSTEM AND SEX HORMONES

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-020	01	No	-	Yes	1: MENOPAUSAL SYMPTOMS	-	-

- : not applicable

Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-020	03	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	-	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-020	03	No	Transdermal	21FEB2019	No	21FEB2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-020	03	No	-	No	-	TRIAL INDICATION	-

- : not applicable

Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-020	02	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	-	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-020	02	Yes	Transdermal	29JAN2019	No	29JAN2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-020	02	No	-	No	-	TRIAL INDICATION	-

- : not applicable

Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-020	04	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	-	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-020	04	No	Transdermal	13MAR2019	No	13MAR2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-020	04	No	-	No	-	TRIAL INDICATION	-

- : not applicable

Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-021	01	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	Yes	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-021	01	Yes	Transdermal	30JAN2019	No	30JAN2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-021	01	No	-	No	-	TRIAL INDICATION	-

- : not applicable

Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-021	02	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	-	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-021	02	No	Transdermal	13MAR2019	No	13MAR2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-021	02	No	-	No	-	TRIAL INDICATION	-

- : not applicable

Listing 11: Prior and concomitant therapy

Part 101 of 182

Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-022	01	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	Yes	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-022	01	Yes	Transdermal	30JAN2019	No	30JAN2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-022	01	No	-	No	-	TRIAL INDICATION	-

- : not applicable

Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-022	02	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	-	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-022	02	No	Transdermal	13MAR2019	No	13MAR2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-022	02	No	-	No	-	TRIAL INDICATION	-

- : not applicable

Listing 11: Prior and concomitant therapy

Part 103 of 182

Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-023	01	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	Yes	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-023	01	Yes	Transdermal	30JAN2019	No	30JAN2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-023	01	No	-	No	-	TRIAL INDICATION	-

- : not applicable

Listing 11: Prior and concomitant therapy

Part 104 of 182

Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-023	02	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	-	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-023	02	No	Transdermal	20FEB2019	No	20FEB2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-023	02	No	-	No	-	TRIAL INDICATION	-

- : not applicable

Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-023	03	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	-	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-023	03	No	Transdermal	13MAR2019	No	13MAR2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-023	03	No	-	No	-	TRIAL INDICATION	-

- : not applicable

Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-024	01	EUTHYROX	Yes	Drug Treatment / Medication	75	ug (Microgram, mcg)	Once Daily (QD)	Tablet

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-024	01	Yes	Oral	UNUNK2016	Yes	-	Level 4: Thyroid hormones Level 3: THYROID PREPARATIONS Level 2: THYROID THERAPY Level 1: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-024	01	No	-	Yes	1: HYPOTHYREOSIS	-	-

- : not applicable

Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-024	02	CALCIVIT D	-	Drug Treatment / Medication	600	mg	Once Daily (QD)	Tablet

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-024	02	Yes	Oral	UNUNK2018	Yes	-	Level 4: Calcium, combinations with vitamin D and/or other drugs Level 3: CALCIUM Level 2: MINERAL SUPPLEMENTS Level 1: ALIMENTARY TRACT AND METABOLISM

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-024	02	No	-	Yes	1: OSTEOPOROSIS	-	-

- : not applicable

Listing 11: Prior and concomitant therapy

Part 108 of 182

Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-024	03	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	-	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-024	03	Yes	Transdermal	30JAN2019	No	30JAN2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-024	03	No	-	No	-	TRIAL INDICATION	-

- : not applicable

Listing 11: Prior and concomitant therapy

Part 109 of 182

Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-025	01	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	Yes	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-025	01	Yes	Transdermal	30JAN2019	No	30JAN2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-025	01	No	-	No	-	TRIAL INDICATION	-

- : not applicable

Listing 11: Prior and concomitant therapy

Part 110 of 182

Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-025	02	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	-	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-025	02	No	Transdermal	06MAR2019	No	06MAR2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-025	02	No	-	No	-	TRIAL INDICATION	-

- : not applicable

Listing 11: Prior and concomitant therapy

Part 111 of 182

Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-026	01	EUTHYROX	Yes	Drug Treatment / Medication	100	ug (Microgram, mcg)	Once Daily (QD)	Tablet

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-026	01	Yes	Oral	UNUNK2013	Yes	-	Level 4: Thyroid hormones Level 3: THYROID PREPARATIONS Level 2: THYROID THERAPY Level 1: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-026	01	No	-	Yes	1: HYPOTHYREOSIS	-	-

- : not applicable

Listing 11: Prior and concomitant therapy

Part 112 of 182

Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-026	02	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	-	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-026	02	Yes	Transdermal	31JAN2019	No	31JAN2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-026	02	No	-	No	-	TRIAL INDICATION	-

- : not applicable

Listing 11: Prior and concomitant therapy

Part 113 of 182

Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-026	03	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	-	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-026	03	No	Transdermal	27FEB2019	No	27FEB2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-026	03	No	-	No	-	TRIAL INDICATION	-

- : not applicable

Listing 11: Prior and concomitant therapy

Part 114 of 182

Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-026	04	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	-	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-026	04	No	Transdermal	13MAR2019	No	13MAR2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-026	04	No	-	No	-	TRIAL INDICATION	-

- : not applicable

Listing 11: Prior and concomitant therapy

Part 115 of 182

Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-027	01	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	Yes	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-027	01	Yes	Transdermal	31JAN2019	No	31JAN2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-027	01	No	-	No	-	TRIAL INDICATION	-

- : not applicable

Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-027	02	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	-	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-027	02	No	Transdermal	20MAR2019	No	20MAR2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-027	02	No	-	No	-	TRIAL INDICATION	-

- : not applicable

Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-028	01	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	Yes	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-028	01	Yes	Transdermal	31JAN2019	No	31JAN2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-028	01	No	-	No	-	TRIAL INDICATION	-

- : not applicable

Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-028	02	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	-	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-028	02	No	Transdermal	20MAR2019	No	20MAR2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-028	02	No	-	No	-	TRIAL INDICATION	-

- : not applicable

Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-029	01	THYREX	Yes	Drug Treatment / Medication	50	ug (Microgram, mcg)	Once Daily (QD)	Tablet

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-029	01	Yes	Oral	UNUNK2014	Yes	-	Level 4: Thyroid hormones Level 3: THYROID PREPARATIONS Level 2: THYROID THERAPY Level 1: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-029	01	No	-	Yes	1: HYPOTHYREOSIS	-	-

- : not applicable

Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-029	02	ACETAN	-	Drug Treatment / Medication	5	mg	Once Daily (QD)	Tablet

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-029	02	Yes	Oral	UNUNK2009	Yes	-	Level 4: ACE inhibitors, plain Level 3: ACE INHIBITORS, PLAIN Level 2: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM Level 1: CARDIOVASCULAR SYSTEM

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-029	02	No	-	Yes	1: HYPERTENSION	-	-

- : not applicable

Listing 11: Prior and concomitant therapy

Part 121 of 182

Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-029	03	CONCOR	-	Drug Treatment / Medication	5	mg	Once Daily (QD)	Tablet

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-029	03	Yes	Oral	UNUNK2009	Yes	-	Level 4: Beta blocking agents, selective Level 3: BETA BLOCKING AGENTS Level 2: BETA BLOCKING AGENTS Level 1: CARDIOVASCULAR SYSTEM

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-029	03	No	-	Yes	1: HYPERTENSION	-	-

- : not applicable

Listing 11: Prior and concomitant therapy

Part 122 of 182

Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-029	04	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	-	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-029	04	Yes	Transdermal	31JAN2019	No	31JAN2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-029	04	No	-	No	-	TRIAL INDICATION	-

- : not applicable

Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-029	05	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	-	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-029	05	No	Transdermal	21FEB2019	No	21FEB2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-029	05	No	-	No	-	TRIAL INDICATION	-

- : not applicable

Listing 11: Prior and concomitant therapy

Part 124 of 182

Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-029	06	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	-	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-029	06	No	Transdermal	14MAR2019	No	14MAR2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-029	06	No	-	No	-	TRIAL INDICATION	-

- : not applicable

Listing 11: Prior and concomitant therapy

Part 125 of 182

Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-030	01	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	Yes	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-030	01	Yes	Transdermal	31JAN2019	No	31JAN2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-030	01	No	-	No	-	TRIAL INDICATION	-

- : not applicable

Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-030	02	GRIPPOSTAD C FORTE GRANULAT	-	Drug Treatment / Medication	1	Sachet	Once Daily (QD)	Effervescent (Granule)

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-030	02	No	Oral	13MAR2019	No	15MAR2019	Level 4: Anilides Level 3: OTHER ANALGESICS AND ANTIPIRETTICS Level 2: ANALGESICS Level 1: NERVOUS SYSTEM

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-030	02	Yes	1: COMMON COLD	No	-	-	-

- : not applicable

Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-031	01	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	Yes	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-031	01	Yes	Transdermal	31JAN2019	No	31JAN2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-031	01	No	-	No	-	TRIAL INDICATION	-

- : not applicable

Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-031	02	EUTHYROX	-	Drug Treatment / Medication	100	ug (Microgram, mcg)	Once Daily (QD)	Tablet

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-031	02	Yes	Oral	UNUNK2005	Yes	-	Level 4: Thyroid hormones Level 3: THYROID PREPARATIONS Level 2: THYROID THERAPY Level 1: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-031	02	No	-	Yes	1: HYPOTHYREOSIS	-	-

- : not applicable

Listing 11: Prior and concomitant therapy

Part 129 of 182

Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-032	01	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	Yes	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-032	01	Yes	Transdermal	31JAN2019	No	31JAN2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-032	01	No	-	No	-	TRIAL INDICATION	-

- : not applicable

Listing 11: Prior and concomitant therapy

Part 130 of 182

Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-032	02	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	-	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-032	02	No	Transdermal	21FEB2019	No	21FEB2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-032	02	No	-	No	-	TRIAL INDICATION	-

- : not applicable

Listing 11: Prior and concomitant therapy

Part 131 of 182

Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-032	03	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	-	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-032	03	No	Transdermal	20MAR2019	No	20MAR2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-032	03	No	-	No	-	TRIAL INDICATION	-

- : not applicable

Listing 11: Prior and concomitant therapy

Part 132 of 182

Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-033	01	DEANXIT	Yes	Drug Treatment / Medication	0.5/10	mg	Once Daily (QD)	Tablet

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-033	01	Yes	Oral	UNUNK2016	Yes	-	Level 4: Antidepressants in combination with psycholeptics Level 3: PSYCHOLEPTICS AND PSYCHOANALEPTICS IN COMBINATION Level 2: PSYCHOANALEPTICS Level 1: NERVOUS SYSTEM

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-033	01	No	-	Yes	1: PANIC ATTACKS	-	-

- : not applicable

Listing 11: Prior and concomitant therapy

Part 134 of 182

Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-033	03	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	-	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-033	03	No	Transdermal	13MAR2019	No	13MAR2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-033	03	No	-	No	-	TRIAL INDICATION	-

- : not applicable

Listing 11: Prior and concomitant therapy

Part 133 of 182

Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-033	02	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	-	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-033	02	Yes	Transdermal	31JAN2019	No	31JAN2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-033	02	No	-	No	-	TRIAL INDICATION	-

- : not applicable

Listing 11: Prior and concomitant therapy

Part 135 of 182

Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-034	01	EUTHYROX	Yes	Drug Treatment / Medication	75	ug (Microgram, mcg)	Once Daily (QD)	Tablet

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-034	01	Yes	Oral	UNUNK2015	Yes	-	Level 4: Thyroid hormones Level 3: THYROID PREPARATIONS Level 2: THYROID THERAPY Level 1: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-034	01	No	-	Yes	1: HYPOTHYREOSIS	-	-

- : not applicable

Listing 11: Prior and concomitant therapy

Part 136 of 182

Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-034	02	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	-	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-034	02	Yes	Transdermal	31JAN2019	No	31JAN2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-034	02	No	-	No	-	TRIAL INDICATION	-

- : not applicable

Listing 11: Prior and concomitant therapy

Part 137 of 182

Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
02-034	03	ANAESTHETIC CREAM - COMPONENTS OF CREME: 10,000 G LIDOCAINE 1,500 G TETRACAINE BASE 1,500 G TETRACAINUM HYDROCHLOR 2,000 G DORITIN 9,000 G ULTRALIP (R) 13,800 G ULTRAPHIL (R) 5,000 G DECODERM BASIS	-	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
02-034	03	No	Transdermal	13MAR2019	No	13MAR2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
02-034	03	No	-	No	-	TRIAL INDICATION	-

- : not applicable

Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
03-001	01	EMLA	Yes	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
03-001	01	No	Topical	06JAN2019	No	06JAN2019	Level 4: Anesthetics for topical use Level 3: ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
03-001	01	No	-	No	-	TRIAL INDICATION	-

- : not applicable

Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
03-002	01	EMLA	Yes	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
03-002	01	Yes	Topical	06JAN2019	No	06JAN2019	Level 4: Anesthetics for topical use Level 3: ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
03-002	01	No	-	No	-	TRIAL INDICATION	-

- : not applicable

Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
03-003	01	EMLA	Yes	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
03-003	01	Yes	Topical	20JAN2019	No	20JAN2019	Level 4: Anesthetics for topical use Level 3: ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
03-003	01	No	-	No	-	TRIAL INDICATION	-

- : not applicable

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Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
03-004	01	EMLA	Yes	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
03-004	01	No	Topical	08JAN2019	No	08JAN2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
03-004	01	No	-	No	-	TRIAL INDICATION	-

- : not applicable

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Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
03-005	01	ELMA	Yes	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
03-005	01	Yes	Topical	20JAN2019	No	20JAN2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
03-005	01	No	-	No	-	TRIAL INDICATION	-

- : not applicable

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Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
03-006	01	EMLA	Yes	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
03-006	01	Yes	Topical	06JAN2019	No	06JAN2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
03-006	01	No	-	No	-	TRIAL INDICATION	-

- : not applicable

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Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
03-007	01	EMLA	Yes	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
03-007	01	No	Topical	08JAN2019	No	08JAN2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
03-007	01	No	-	No	-	TRIAL INDICATION	-

- : not applicable

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Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
03-008	01	EMLA	Yes	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
03-008	01	Yes	Topical	20JAN2019	No	20JAN2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
03-008	01	No	-	No	-	TRIAL INDICATION	-

- : not applicable

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Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
03-009	01	EMLA	Yes	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
03-009	01	Yes	Topical	20JAN2019	No	20JAN2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
03-009	01	No	-	No	-	TRIAL INDICATION	-

- : not applicable

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
03-010	01	EMLA	Yes	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
03-010	01	No	Topical	08JAN2019	No	08JAN2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
03-010	01	No	-	No	-	TRIAL INDICATION	-

- : not applicable

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Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
03-011	01	EMLA	Yes	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
03-011	01	No	Topical	06JAN2019	No	06JAN2019	Level 4: Anesthetics for topical use Level 3: ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
03-011	01	No	-	No	-	TRIAL INDICATION	-

- : not applicable

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
03-012	01	EMLA	Yes	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
03-012	01	Yes	Topical	20JAN2019	No	20JAN2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
03-012	01	No	-	No	-	TRIAL INDICATION	-

- : not applicable

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Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
03-013	01	EMLA	Yes	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
03-013	01	No	Topical	06JAN2019	No	06JAN2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
03-013	01	No	-	No	-	TRIAL INDICATION	-

- : not applicable

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Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
03-014	01	EMLA	Yes	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
03-014	01	Yes	Topical	06JAN2018	No	06JAN2018	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
03-014	01	No	-	No	-	TRIAL INDICATION	-

- : not applicable

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Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
03-016	01	EMLA	Yes	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
03-016	01	Yes	Topical	20JAN2019	No	20JAN2019	Level 4: Anesthetics for topical use Level 3: ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
03-016	01	No	-	No	-	TRIAL INDICATION	-

- : not applicable

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
03-015	01	EMLA	Yes	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
03-015	01	No	Topical	06JAN2019	No	06JAN2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
03-015	01	No	-	No	-	TRIAL INDICATION	-

- : not applicable

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Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
03-017	01	EMLA	Yes	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
03-017	01	Yes	Topical	20JAN2019	No	20JAN2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
03-017	01	No	-	No	-	TRIAL INDICATION	-

- : not applicable

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
03-019	01	EMLA	Yes	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
03-019	01	Yes	Topical	08JAN2018	No	08JAN2018	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
03-019	01	No	-	No	-	TRIAL INDICATION	-

- : not applicable

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
03-018	01	EMLA	Yes	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
03-018	01	No	Topical	08JAN2019	No	08JAN2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
03-018	01	No	-	No	-	TRIAL INDICATION	-

- : not applicable

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
03-020	01	EMLA	Yes	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
03-020	01	No	Topical	06JAN2019	No	06JAN2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
03-020	01	No	-	No	-	TRIAL INDICATION	-

- : not applicable

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Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
03-021	01	EMLA	Yes	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
03-021	01	No	Topical	08JAN2019	No	08JAN2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
03-021	01	No	-	No	-	TRIAL INDICATION	-

- : not applicable

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit IU (International Units)	Dosing frequency per interval	Dosage form
03-020	02	HYALURONIDASE	-	Drug Treatment / Medication	150		Once	Injection

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
03-020	02	No	Subcutaneous	02DEC2018	No	02DEC2018	Level 4: Enzymes Level 3: OTHER HEMATOLOGICAL AGENTS Level 2: OTHER HEMATOLOGICAL AGENTS Level 1: BLOOD AND BLOOD FORMING ORGANS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
03-020	02	Yes	1: EDEMA AT INJECTION SITE RIGHT 2: EDEMA AT INJECTION SITE LEFT	No	-	TRIAL INDICATION	-

- : not applicable

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Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
03-022	01	EMLA	Yes	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
03-022	01	Yes	Topical	20JAN2019	No	20JAN2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
03-022	01	No	-	No	-	TRIAL INDICATION	-

- : not applicable

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
03-023	01	EMLA	Yes	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
03-023	01	No	Topical	06JAN2019	No	06JAN2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
03-023	01	No	-	No	-	TRIAL INDICATION	-

- : not applicable

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Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
03-024	01	EMLA	Yes	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
03-024	01	Yes	Topical	08JAN2018	No	08JAN2018	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
03-024	01	No	-	No	-	TRIAL INDICATION	-

- : not applicable

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Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
03-025	01	EMLA	Yes	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
03-025	01	Yes	Topical	20JAN2019	No	20JAN2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
03-025	01	No	-	No	-	TRIAL INDICATION	-

- : not applicable

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Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
03-026	01	EMLA	Yes	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
03-026	01	No	Topical	08JAN2019	No	08JAN2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
03-026	01	No	-	No	-	TRIAL INDICATION	-

- : not applicable

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
03-027	01	EMLA	Yes	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
03-027	01	Yes	Topical	08JAN2019	No	08JAN2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
03-027	01	No	-	No	-	TRIAL INDICATION	-

- : not applicable

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
03-028	01	EMLA	Yes	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
03-028	01	Yes	Topical	20JAN2019	No	20JAN2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
03-028	01	No	-	No	-	TRIAL INDICATION	-

- : not applicable

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
03-029	01	EMLA	Yes	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
03-029	01	Yes	Topical	20JAN2019	No	20JAN2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
03-029	01	No	-	No	-	TRIAL INDICATION	-

- : not applicable

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
03-030	01	EMLA	Yes	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
03-030	01	Yes	Topical	20JAN2019	No	20JAN2019	Level 4: Anesthetics for topical use Level 3: ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
03-030	01	No	-	No	-	TRIAL INDICATION	-

- : not applicable

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
03-030	02	EMLA	-	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
03-030	02	Yes	Topical	03MAR2019	No	03MAR2019	Level 4: Anesthetics for topical use Level 3: ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
03-030	02	No	-	No	-	TRIAL INDICATION	-

- : not applicable

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
03-031	-	-	No	-	-	-	-	-

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
03-031	-	-	-	-	-	-	-

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
03-031	-	-	-	-	-	-	-

- : not applicable

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Listing 11: Prior and concomitant therapy

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Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
03-032	01	EMLA	Yes	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
03-032	01	Yes	Topical	20JAN2019	No	20JAN2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
03-032	01	No	-	No	-	TRIAL INDICATION	-

- : not applicable

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Listing 11: Prior and concomitant therapy

Part 172 of 182

Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
03-033	-	-	No	-	-	-	-	-

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
03-033	-	-	-	-	-	-	-

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
03-033	-	-	-	-	-	-	-

- : not applicable

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Listing 11: Prior and concomitant therapy

Part 173 of 182

Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
03-034	-	-	No	-	-	-	-	-

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
03-034	-	-	-	-	-	-	-

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
03-034	-	-	-	-	-	-	-

- : not applicable

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Listing 11: Prior and concomitant therapy

Part 174 of 182

Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
03-035	-	-	No	-	-	-	-	-

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
03-035	-	-	-	-	-	-	-

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
03-035	-	-	-	-	-	-	-

- : not applicable

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Listing 11: Prior and concomitant therapy

Part 175 of 182

Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
03-036	-	-	No	-	-	-	-	-

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
03-036	-	-	-	-	-	-	-

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
03-036	-	-	-	-	-	-	-

- : not applicable

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Listing 11: Prior and concomitant therapy

Part 177 of 182

Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
03-038	-	-	No	-	-	-	-	-

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
03-038	-	-	-	-	-	-	-

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
03-038	-	-	-	-	-	-	-

- : not applicable

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Listing 11: Prior and concomitant therapy

Part 176 of 182

Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
03-037	-	-	No	-	-	-	-	-

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
03-037	-	-	-	-	-	-	-

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
03-037	-	-	-	-	-	-	-

- : not applicable

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Listing 11: Prior and concomitant therapy

Part 178 of 182

Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
03-039	-	-	No	-	-	-	-	-

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
03-039	-	-	-	-	-	-	-

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
03-039	-	-	-	-	-	-	-

- : not applicable

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Listing 11: Prior and concomitant therapy

Part 179 of 182

Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
03-040	-	-	No	-	-	-	-	-

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
03-040	-	-	-	-	-	-	-

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
03-040	-	-	-	-	-	-	-

- : not applicable

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Listing 11: Prior and concomitant therapy

Part 180 of 182

Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
03-041	-	-	No	-	-	-	-	-

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
03-041	-	-	-	-	-	-	-

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
03-041	-	-	-	-	-	-	-

- : not applicable

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Listing 11: Prior and concomitant therapy

Part 181 of 182

Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
03-042	01	EMLA	Yes	Drug Treatment / Medication	1	Application	Once	Cream

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
03-042	01	Yes	Topical	20JAN2019	No	20JAN2019	Level 4: Anesthetics for topical use Level 3: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 2: ANTIPTURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC. Level 1: DERMATOLOGICALS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
03-042	01	No	-	No	-	TRIAL INDICATION	-

- : not applicable

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Listing 11: Prior and concomitant therapy

Part 182 of 182

Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
03-043	-	-	No	-	-	-	-	-

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
03-043	-	-	-	-	-	-	-

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
03-043	-	-	-	-	-	-	-

- : not applicable

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Listing 12: Completion of trial / discontinuation from trial / screening failure

Part 1 of 5

Center	Site ID / Screening No.	Did the subject complete the study as planned?	If no, the subject was discontinued for the following reason	If other or withdrawal by subject, please specify	Date of completion / withdrawal	Relative day to start of treatment	Any comments?
Dermatology and venerology clinic	01-001	Yes	-	-	24MAY2019	123	No
	01-002	Yes	-	-	27MAY2019	126	No
	01-003	No	WITHDRAWAL BY SUBJECT	PERSONAL REASONS	09APR2019	78	No
	01-004	Yes	-	-	22MAY2019	121	No
	01-005	Yes	-	-	27MAY2019	126	No
	01-006	Yes	-	-	24MAY2019	123	No
	01-007	Yes	-	-	22MAY2019	111	No
	01-008	No	OTHER	NO AESTHETIC EFFECT AT VISIT 7	07AUG2019	188	No
	01-009	No	OTHER	NO AESTHETIC EFFECT AT VISIT 7	07AUG2019	188	No
	01-010	No	OTHER	NO AESTHETIC EFFECT AT V8	22OCT2019	264	No
	01-011	Yes	-	-	23MAY2019	109	No
	01-012	Yes	-	-	23MAY2019	109	No
	01-013	Yes	-	-	20MAY2019	106	No
	01-014	Yes	-	-	27MAY2019	113	No
	01-015	Yes	-	-	28MAY2019	113	No
	01-016	Yes	-	-	27MAY2019	112	No
	01-017	No	OTHER	NO AESTHETIC EFFECT AT VISIT 7	22JUL2019	168	No
	01-018	Yes	-	-	27MAY2019	112	No
	01-019	Yes	-	-	27MAY2019	112	No
	01-020	No	OTHER	NO AESTHETIC EFFECT AT VISIT 7	04SEP2019	212	No
	01-021	No	OTHER	NO AESTHETIC EFFECT AT VISIT 7	07AUG2019	184	No

- : not applicable

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Listing 12: Completion of trial / discontinuation from trial / screening failure

Part 2 of 5

Center	Site ID / Screening No.	Did the subject complete the study as planned?	If no, the subject was discontinued for the following reason	If other or withdrawal by subject, please specify	Date of completion / withdrawal	Relative day to start of treatment	Any comments?
Dermatology and venerology clinic	01-022	No	OTHER	PATIENT SUFFERS FROM FAMILIAL CATESTROPHES (FATHER DIED AND DAUGHTER SUFFERS FROM BREAST CANCER). PATIENT WANTS TO QUIT THE STUDY.	05MAR2019	23	No
	01-023	Yes	-	-	12JUN2019	120	No
	01-024	Yes	-	-	04JUN2019	112	No
	01-025	Yes	-	-	03JUN2019	109	No
Yuvell fine aesthetics	02-001	Yes	-	-	14FEB2019	113	No
	02-002	Yes	-	-	20FEB2019	119	No
	02-003	Yes	-	-	14FEB2019	113	No
	02-004	Yes	-	-	14FEB2019	113	No
	02-005	Yes	-	-	14FEB2019	113	No
	02-006	Yes	-	-	27FEB2019	112	No
	02-007	Yes	-	-	06MAR2019	112	No
	02-008	Yes	-	-	15MAY2019	113	No
	02-009	Yes	-	-	15MAY2019	113	No
	02-010	Yes	-	-	15MAY2019	113	No
	02-011	Yes	-	-	15MAY2019	112	No
	02-012	Yes	-	-	15MAY2019	112	No
	02-013	Yes	-	-	09MAY2019	106	No
	02-014	Yes	-	-	15MAY2019	112	No
	02-015	Yes	-	-	15MAY2019	112	No
	02-016	Yes	-	-	15MAY2019	112	No
	02-017	Yes	-	-	16MAY2019	113	No

- : not applicable

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Listing 12: Completion of trial / discontinuation from trial / screening failure

Part 3 of 5

Center	Site ID / Screening No.	Did the subject complete the study as planned?	If no, the subject was discontinued for the following reason	If other or withdrawal by subject, please specify	Date of completion / withdrawal	Relative day to start of treatment	Any comments?
Yuvell fine aesthetics	02-018	Yes	-	-	16MAY2019	108	No
	02-019	Yes	-	-	23MAY2019	115	No
	02-020	Yes	-	-	23MAY2019	115	No
	02-021	Yes	-	-	23MAY2019	114	No
	02-022	No	OTHER	NO AESTHETIC EFFECT AT VISIT 8	02OCT2019	246	No
	02-023	No	OTHER	NO AESTHETIC EFFECT AT VISIT 8	09OCT2019	253	No
	02-024	Yes	-	-	23MAY2019	114	No
	02-025	No	OTHER	COMPLETED AS PLANNED ACCORDING TO CIP SECTION 16, 75% OF SUBJECTS WITHOUT AESTHETIC EFFECT	02OCT2019	246	No
	02-026	Yes	-	-	29MAY2019	119	No
	02-027	No	OTHER	NO AESTHETIC EFFECT AT VISIT 8	10OCT2019	253	No
	02-028	No	OTHER	COMPLETED AS PLANNED ACCORDING TO CIP SECTION 16, 75% OF SUBJECTS WITHOUT AESTHETIC EFFECT	02OCT2019	245	No
	02-029	Yes	-	-	23MAY2019	113	No
	02-030	Yes	-	-	23MAY2019	113	No
	02-031	Yes	-	-	23MAY2019	113	No
	02-032	Yes	-	-	22MAY2019	112	No
	02-033	No	OTHER	NO AESTHETIC EFFECT AT VISIT 8	09OCT2019	252	No
	02-034	Yes	-	-	22MAY2019	112	No
Mara Graz	03-001	Yes	-	-	17MAR2019	113	No
	03-002	Yes	-	-	17MAR2019	113	No
	03-003	Yes	-	-	05MAY2019	106	No
	03-004	Yes	-	-	21MAR2019	113	No

- : not applicable

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Listing 12: Completion of trial / discontinuation from trial / screening failure

Part 4 of 5

Center	Site ID / Screening No.	Did the subject complete the study as planned?	If no, the subject was discontinued for the following reason	If other or withdrawal by subject, please specify	Date of completion / withdrawal	Relative day to start of treatment	Any comments?
Mara Graz	03-005	Yes	-	-	05MAY2019	106	No
	03-006	Yes	-	-	16MAR2019	112	No
	03-007	Yes	-	-	20MAR2019	112	No
	03-008	Yes	-	-	05MAY2019	106	No
	03-009	Yes	-	-	05MAY2019	106	No
	03-010	Yes	-	-	17MAR2019	109	No
	03-011	Yes	-	-	17MAR2019	113	No
	03-012	Yes	-	-	05MAY2019	106	No
	03-013	Yes	-	-	17MAR2019	113	No
	03-014	Yes	-	-	17MAR2019	113	No
	03-015	Yes	-	-	16MAR2019	112	No
	03-016	Yes	-	-	14MAY2019	115	No
	03-017	Yes	-	-	05MAY2019	106	No
	03-018	Yes	-	-	16MAR2019	108	Yes: THE PATIENT WOULDN'T RECOMMEND THE TREATMENT
	03-019	Yes	-	-	16MAR2019	108	No
	03-020	Yes	-	-	17MAR2019	113	No
	03-021	Yes	-	-	16MAR2019	108	No
	03-022	Yes	-	-	05MAY2019	106	No
	03-023	Yes	-	-	17MAR2019	113	No
	03-024	Yes	-	-	16MAR2019	108	Yes: THE PATIENT MENTIONED, THAT SHE WOULDN'T DO THIS TREATMENT AGAIN
	03-025	Yes	-	-	05MAY2019	106	No

- : not applicable

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Listing 12: Completion of trial / discontinuation from trial / screening failure

Part 5 of 5

Center	Site ID / Screening No.	Did the subject complete the study as planned?	If no, the subject was discontinued for the following reason	If other or withdrawal by subject, please specify	Date of completion / withdrawal	Relative day to start of treatment	Any comments?
Mara Graz	03-026	Yes	-	-	16MAR2019	108	No
	03-027	Yes	-	-	16MAR2019	108	No
	03-028	Yes	-	-	05MAY2019	106	No
	03-029	Yes	-	-	14MAY2019	115	No
	03-030	Yes	-	-	05MAY2019	106	No
	03-031	Yes	-	-	14MAY2019	110	No
	03-032	Yes	-	-	05MAY2019	106	No
	03-033	Yes	-	-	14MAY2019	109	No
	03-034	Yes	-	-	14MAY2019	110	No
	03-035	Yes	-	-	14MAY2019	109	No
	03-036	Yes	-	-	14MAY2019	109	No
	03-037	Yes	-	-	14MAY2019	110	No
	03-038	Yes	-	-	14MAY2019	110	No
	03-039	Yes	-	-	14MAY2019	109	No
	03-040	Yes	-	-	14MAY2019	110	No
	03-041	Yes	-	-	14MAY2019	110	No
	03-042	Yes	-	-	14MAY2019	115	No
	03-043	Yes	-	-	14MAY2019	109	No

- : not applicable

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Treatment administration

Listing 13: Device administration

Part 1 of 75

Anesthetic and rescue medication				Device administration										
Center	Site ID / Screening No.	Visit	Any anesthetic used?	Type	Time	Hyaluronidase used as a rescue medication?	Technique	Date if unequal to visit date	Test field/ area	Done?	Reason not done	Start time	End time	Injected volume
Dermatology and venerology clinic	01-001	Day 0	No	-	-	No	MULTIPUNCTURE		RIGHT LCL	Yes	-	11:50	12:00	0.3
									LEFT LCL	Yes	-	12:00	12:02	0.3
									PR	Yes	-	12:06	12:09	0.5
		Week 3	No	-	-	No	MULTIPUNCTURE		RIGHT LCL	Yes	-	16:44	16:45	0.3
									LEFT LCL	Yes	-	16:46	16:47	0.3
									PR	Yes	-	16:48	16:50	0.3
	Week 6	No	-	-	No	MULTIPUNCTURE		RIGHT LCL	Yes	-	14:30	14:31	0.5	
								LEFT LCL	Yes	-	14:32	14:33	0.5	
								PR	Yes	-	14:34	14:35	0.5	
	01-002	Day 0	No	-	-	No	MULTIPUNCTURE		RIGHT LCL	Yes	-	12:41	12:43	0.3
									LEFT LCL	Yes	-	12:44	12:46	0.3
									PR	Yes	-	12:47	12:48	0.3

- : not applicable

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Listing 13: Device administration

Part 2 of 75

			Anesthetic and rescue medication				Device administration							
Center	Site ID / Screening No.	Visit	Any anesthetic used?	Type	Time	Hyaluronidase used as a rescue medication?	Technique	Date if unequal to visit date	Test field/ area	Done?	Reason not done	Start time	End time	Injected volume
Dermatology and venerology clinic	01-002	Week 6	No	-	-	No	MULTIPUNCTURE		RIGHT LCL	Yes	-	09:03	09:04	0.3
									LEFT LCL	Yes	-	09:05	09:06	0.3
									PR	No	PATIENT DIDN'T WANT TO	-	-	-
	01-003	Day 0	No	-	-	No	MULTIPUNCTURE		RIGHT LCL	Yes	-	13:51	13:53	0.3
									LEFT LCL	Yes	-	13:54	13:56	0.3
									PR	Yes	-	13:57	13:59	0.3
		Week 6	No	-	-	No	MULTIPUNCTURE		RIGHT LCL	Yes	-	11:08	11:09	0.5
									LEFT LCL	Yes	-	11:10	11:11	0.5
									PR	No	OPTIMAL RESULT	-	-	-
	01-004	Day 0	No	-	-	No	MULTIPUNCTURE		RIGHT LCL	Yes	-	14:42	14:44	0.3
									LEFT LCL	Yes	-	14:45	14:47	0.3
									PR	Yes	-	14:48	14:50	0.3

- : not applicable

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Listing 13: Device administration

Part 3 of 75

			Anesthetic and rescue medication				Device administration							
Center	Site ID / Screening No.	Visit	Any anesthetic used?	Type	Time	Hyaluronidase used as a rescue medication?	Technique	Date if unequal to visit date	Test field/ area	Done?	Reason not done	Start time	End time	Injected volume
Dermatology and venerology clinic	01-004	Week 3	No	-	-	No	MULTIPUNCTURE		RIGHT LCL	Yes	-	10:20	10:21	0.3
									LEFT LCL	Yes	-	10:22	10:23	0.3
									PR	No	PATIENT DIDN'T WANT IMD IN LIPS ANYMORE	-	-	-
		Week 6							RIGHT LCL	No	PATIENT DID NOT WANT MORE IMD	-	-	-
									LEFT LCL	No	PATIENT DID NOT WANT MORE IMD	-	-	-
									PR	No	PATIENT DID NOT WANT MORE IMD	-	-	-
	01-005	Day 0	No	-	-	No	MULTIPUNCTURE		RIGHT LCL	Yes	-	15:45	15:47	0.3
									LEFT LCL	Yes	-	15:48	15:50	0.3
									PR	Yes	-	15:51	15:53	0.3
		Week 3	No	-	-	No	MULTIPUNCTURE		RIGHT LCL	Yes	-	13:10	13:11	0.3
									LEFT LCL	Yes	-	13:12	13:13	0.3
									PR	Yes	-	13:14	13:15	0.3

- : not applicable