



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

30 November 2017
EMA/817351/2017
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: Lidocaine / prilocaine (not centrally authorised product)

Procedure no.: PSUSA/00001867/201703



Product Name (in authorisation country)	MRP/DCP Authorisation Number	National Authorisation Number	MAH of product in the Member State	Member State where product is authorised
LIDOCAINE / PRILOCAINE ZENTIVA 5 % PANSEMENT ADHESIF CUTANE	not available	34009 276 655 1 6	SANOFI-AVENTIS FRANCE	FR
EMLA, 25 mg/g + 25 mg/g, creme	UK/H/6112/001	2443588	ASTRAZENECA PRODUTOS FARMACEUTICOS LDA	PT
EMLA 25 mg/g + 25 mg/g cream	not available	12900	ASTRAZENECA AB	CY
Emla	UK/H/6112/001	11694	ASTRAZENECA A/S	DK
EMLA® emulsiovoide	not available	9139	ASTRAZENECA OY	FI
Emla® Creme	UK/H/6112/001	42850.00.00	ASTRAZENECA GMBH	DE
EMLA 2,5%+2,5% crema	not available	27756016	ASTRAZENECA S.P.A.	IT
EMLA 5% w/w Cream	not available	PA 970/38/1	ASTRAZENECA UK LIMITED	IE
EMLA 2,5%+2,5% crema	not available	27756030	ASTRAZENECA S.P.A.	IT
emla, hydrofiele crème 5%	not available	RVG11015	ASTRAZENECA BV	NL
EMLA 5% w/w Cream	FI/H/0886/001	MA046/00401	ASTRAZENECA AB	MT
EMLA 25 mg/g + 25 mg/g crema	not available	61.096	ASTRAZENECA FARMACÉUTICA SPAIN, S.A.	ES
EMLA, 25 mg/g + 25 mg/g, krem	FI/H/0886/001	R/3733	ASTRAZENECA AB	PL
EMLA Penso, 25 mg/g + 25 mg/g, penso impregnado	not available	2426286	ASTRAZENECA PRODUTOS FARMACEUTICOS LDA	PT
EMLA 25 mg/g + 25 mg/g crema	not available	61.095	ASTRAZENECA FARMACÉUTICA SPAIN, S.A.	ES
Emla 25 mg/g+25 mg/g, kräm	not available	10129	ASTRAZENECA AB	SE
EMLA Penso, 25 mg/g + 25 mg/g, penso impregnado	not available	2426385	ASTRAZENECA PRODUTOS FARMACEUTICOS LDA	PT
Emla 25 mg/25 mg, medicinskt plåster	not available	11834	ASTRAZENECA AB	SE

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EMLA PLASTER, 25 mg + 25 mg, plaster leczniczy	not available	8104	ASTRAZENECA AB	PL
emla, pleister	not available	RVG15721	ASTRAZENECA BV	NL
Emla® Pflaster wirkstoffhaltiges Pflaster Lidocain und Prilocain	not available	34386.00.00	ASTRAZENECA GMBH	DE
Emla, medicinsk plaster	not available	14511	ASTRAZENECA A/S	DK
EMLA® laastari	not available	11058	ASTRAZENECA OY	FI
EMLA 5% krēms	FI/H/0886/001	00-0823	ASTRAZENECA AB	LV
EMLA 25 mg/g + 25 mg/g krém	UK/H/6112/001	01/942/97-C	ASTRAZENECA UK LIMITED	CZ
EMLA 25 mg/25 mg medisiner plaster	not available	8112	ASTRAZENECA AS	NO
Emla 25 mg/g + 25 mg/g krem	FI/H/0886/001	7215	ASTRAZENECA AS	NO
Emla lyfjaplástur	not available	910073	ASTRAZENECA A/S	IS
Emla 25 mg/g + 25 mg/g krem	FI/H/0886/001	843429	ASTRAZENECA A/S	IS
Emla® Pflaster wirkstoffhaltiges Pflaster Lidocain und Prilocain	not available	1-2150	ASPEN PHARMA TRADING LIMITED	AT
Emla 5% - Creme	not available	1-21507	ASPEN PHARMA TRADING LIMITED	AT
EMLA® Cream 5%	not available	PL 39699/0088	ASPEN PHARMA TRADING LIMITED	UK
EMLA 25 mg/g + 25 mg/g crème	FI/H/0886/01	2011010957	ASPEN PHARMA TRADING LIMITED	LU
EMLA Patch, 25mg / 25mg emplâtre médicamenteux	not available	2011010958	ASPEN PHARMA TRADING LIMITED	LU

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EMLA Patch, 25 mg/25 mg, wirkstoffhaltiges Pflaster	not available	2011010958	ASPEN PHARMA TRADING LIMITED	LU
EMLA 25 mg/g + 25 mg/g Creme	FI/H/0886/01	2011010957	ASPEN PHARMA TRADING LIMITED	LU
EMLAPATCH 5 POUR CENT, pansement adhésif cutané	not available	34009 558 875 9 1	ASPEN PHARMA TRADING LIMITED	FR
EMLAPATCH 5 POUR CENT, pansement adhésif cutané	not available	34009 339 110 7 2	ASPEN PHARMA TRADING LIMITED	FR
EMLAPATCH 5 POUR CENT, pansement adhésif cutané	not available	34009 340 007 1 3	ASPEN PHARMA TRADING LIMITED	FR
EMLA® 5 POUR CENT, crème	not available	34009 556 938 3 3	ASPEN PHARMA TRADING LIMITED	FR
EMLA® 5 POUR CENT, crème	not available	34009 556 937 7 2	ASPEN PHARMA TRADING LIMITED	FR
EMLA® 5 POUR CENT, crème	not available	34009 556 935 4 3	ASPEN PHARMA TRADING LIMITED	FR
EMLA® 5 POUR CENT, crème	not available	34009 559 145 4 9	ASPEN PHARMA TRADING LIMITED	FR
EMLA® 5 POUR CENT, crème	not available	34009 332 923 2 4	ASPEN PHARMA TRADING LIMITED	FR
EMLA® 5 POUR CENT, crème	not available	34009 556 936 0 4	ASPEN PHARMA TRADING LIMITED	FR
EMLA, 25mg / 25mg crème	FI/H/0886/001	BE177055	ASPEN PHARMA TRADING LIMITED	BE
EMLA, 25mg / 25mg crème	FI/H/0886/001	BE177055	ASPEN PHARMA TRADING LIMITED	BE
EMLA Patch, 25mg / 25mg emplâtre médicamenteux	not available	BE139142	ASPEN PHARMA TRADING LIMITED	BE

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EMLA Patch, 25 mg / 25 mg pleister	not available	BE139142	ASPEN PHARMA TRADING LIMITED	BE
EMLA Patch, 25 mg / 25 mg wirkstoffhaltiges Pflaster	not available	BE139142	ASPEN PHARMA TRADING LIMITED	BE
EMLA 25 mg/g + 25 mg/g Creme	FI/H/0886/001	BE177055	ASPEN PHARMA TRADING LIMITED	BE
EMLATM κρέμα (2,5+2,5)%	FI/H/0886/001	78819/16/22-03-2017	ASPEN PHARMA TRADING LIMITED	GR
EMLATM Έμπλαστρο φαρμακούχο (2,5 + 2,5) % W/W	not available	78818/16/22-03-17	ASPEN PHARMA TRADING LIMITED	GR
EMLA 2,5%+2,5% crema.	FI/H/0886/001	027756028	ASTRAZENECA S.P.A.	IT
Lidocaine/Prilocaine Teva 25 + 25 mg/g crème	DK/H/2368/001	RVG 115128	TEVA NEDERLAND B.V.	NL
Lidocaina e Prilocaina Teva (2,5/2,5)% crema	DK/H/2368/001	043453036	TEVA ITALIA S.R.L.	IT
Lidocaina e Prilocaina Teva (2,5/2,5)% crema	DK/H/2368/001	043453012	TEVA ITALIA S.R.L.	IT
Lidocaina e Prilocaina Teva (2,5/2,5)% crema	DK/H/2368/001	043453024	TEVA ITALIA S.R.L.	IT
Lipricain, creme	DK/H/2368/001	53794	TEVA DENMARK A/S	DK
ANESTOPIC 25 mg/g + 25 mg/g crema	not available	78664	MESOESTETIC PHARMA GROUP S.L.	ES
Oraqix, gel periodontal	SE/H/0426/001	1538/05025001	DENTSPLY DETREY	LU
Oraqix Periodontal gel	SE/H/0426/001	PL 4690/0033	DENTSPLY LIMITED	UK
Oraqix tannholdshlaup	SE/H/0426/001	IS/1/04/030/01	DENTSPLY DETREY	IS

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Oraqix, gel periodontal	SE/H/0426/001	BE288601	DENTSPLY DETREY	BE
Oraqix Parodontal-Gel	SE/H/0426/001	59618.00.00	DENTSPLY DETREY	DE
Oraqix periodontalgel	SE/H/0426/001	36518	DENTSPLY DETREY	DK
Oraqix Gel Periodontal	SE/H/0426/001	66719	DENTSPLY DETREY	ES
Oraqix-geeli ientaskuun	SE/H/0426/001	19429	DENTSPLY DETREY	FI
ORAQIX, gel périodontal	SE/H/0426/001	367 881-4	DENTSPLY FRANCE	FR
Oraqix 25/25 mg per g Periodontal gel	SE/H/0426/001	PA 1045/4/1	DENTSPLY LIMITED	IE
Oraqix gel periodontale	SE/H/0426/001	037590015	DENTSPLY ITALIA	IT
Oraqix, gel voor peri-odontaal gebruik 25 mg/g + 25 mg/g	SE/H/0426/001	RVG 30847	DENTSPLY DETREY	NL
Oraqix periodontalgel	SE/H/0426/001	04-2648	DENTSPLY DETREY	NO
Oraqix periodontalgel	SE/H/0426/001	18344	DENTSPLY LIMITED	SE
Nulbia 25 mg/g + 25mg/g creme	DK/H/2484/001/DC	55929	TERIX LABS LTD	DK
Nulbia 5% cream	DK/H/2484/001	PL 25258/0225	GLENMARK PHARMACEUTICALS EUROPE LIMITED	UK
ROMLA 25mg/25mg/g cremă	DK/H/2484/001	9076/2016/01	ELANTIS FARMA S.R.L.	RO
ROMLA 25mg/25mg/g cremă	DK/H/2484/001	9076/2016/02	ELANTIS FARMA S.R.L.	RO
ROMLA 25mg/25mg/g cremă	DK/H/2484/001	9076/2016/03	ELANTIS FARMA S.R.L.	RO
ROMLA 25mg/25mg/g cremă	DK/H/2484/001	9076/2016/04	ELANTIS FARMA S.R.L.	RO
ROMLA 25mg/25mg/g cremă	DK/H/2484/001	9076/2016/05	ELANTIS FARMA S.R.L.	RO

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ROMLA 25mg/25mg/g crema	DK/H/2484/001	9076/2016/06	ELANTIS FARMA S.R.L.	RO
Motti, 25 mg/g + 25 mg/g, krem	DK/H/2484/001	23504	ZAKLADY FARMACEUTYCZNE "POLPHARMA" SPOLKA AKCYJNA	PL
РОМЛА 25 mg/25 mg/g крем	DK/H/2484/001	20160418	ELANTIS FARMA S.R.L.	BG
РОМЛА 25 mg/25 mg/g крем	DK/H/2484/001	20160418	ELANTIS FARMA S.R.L.	BG
РОМЛА 25 mg/25 mg/g крем	DK/H/2484/001	20160418	ELANTIS FARMA S.R.L.	BG
РОМЛА 25 mg/25 mg/g крем	DK/H/2484/001	20160418	ELANTIS FARMA S.R.L.	BG
РОМЛА 25 mg/25 mg/g крем	DK/H/2484/001	20160418	ELANTIS FARMA S.R.L.	BG
РОМЛА 25 mg/25 mg/g крем	DK/H/2484/001	20160418	ELANTIS FARMA S.R.L.	BG
Lidokain/Prilokain Alternova 25 mg/g + 25 mg/g kräm	DK/H/2484/001	52733	ALTERNOVA A/S	SE
ANESTEAL 25mg/g+25mg/g crema	DE/H/2194/001	73848	PIERRE FABRE IBERICA, S.A.	ES
ANESDERM 25 mg/ g + 25 mg/ g crema	DE/H/2194/001	041900034	PIERRE FABRE ITALIA S.P.A.	IT
ANESDERM 25 mg/ g + 25 mg/ g crema	DE/H/2194/001	041900010	PIERRE FABRE ITALIA S.P.A.	IT
ANESDERM 25 mg/ g + 25 mg/ g crema	DE/H/2194/001	041900022	PIERRE FABRE ITALIA S.P.A.	IT
ANESDERM 25 mg/g + 25 mg/g Crema	DE/H/2194/001	75572.00.00	PIERRE FABRE DERMO- KOSMETIK GMBH	DE
Anesderm, (25 mg + 25 mg)/g, krem	DE/H/2194/001	17998	PIERRE FABRE DERMATOLOGIE	PL
Tapin 25 mg/25 mg medisinert plaster	DK/H/2316/001	13-9558	ORIFARM GENERICS A/S	NO

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Tapin 25 mg / 25 mg lääkelaastari	DK/H/2316/001	31568	ORIFARM GENERICS A/S	FI
Tapin 25 mg/25 mg medicinskt plåster	DK/H/2316/001	49407	ORIFARM GENERICS A/S	SE
Tapin, medicinsk plaster	DK/H/2316/001	52480	ORIFARM GENERICS A/S	DK
ANESDERM 5%, crème	not available	34009 368 636 3 7	SAS PIERRE FABRE DERMATOLOGIE	FR
ANESDERM 5%, crème	not available	34009 382 023 5 9	SAS PIERRE FABRE DERMATOLOGIE	FR
ANESDERM 5%, crème	not available	34009 566 400 6 5	SAS PIERRE FABRE DERMATOLOGIE	FR
Denela, creme	UK/H/3229/001	53689	AUDEN MCKENZIE (PHARMA DIVISION) LTD	DK
Denela 5% Cream	UK/H/3229/001	MA561/00801	AUDEN MCKENZIE (PHARMA DIVISION) LTD	MT
Denela 50 mg/g crème	UK/H/3229/001	RVG 114867	AUDEN MCKENZIE (PHARMA DIVISION) LTD	NL
Denela 25 mg/g + 25 mg/g kräm	UK/H/3229/001	50703	AUDEN MCKENZIE (PHARMA DIVISION) LTD	SE
Denela 5% Κρέμα	UK/H/3229/001	3069101	AUDEN MCKENZIE (PHARMA DIVISION) LTD	GR
Denela 5% Cream	UK/H/3229/001	PL 17507/0119	AUDEN MCKENZIE (PHARMA DIVISION) LTD	UK
Denela 5% Cream	UK/H/3229/001	PA1352/021/001	AUDEN MCKENZIE (PHARMA DIVISION) LTD	IE
Denela	UK/H/3229/001	22341	AUDEN MCKENZIE (PHARMA DIVISION) LTD	PL

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Lidocaina e Prilocaina Auden 2,5% + 2,5% crema	UK/H/3229/001	043299015	AUDEN MCKENZIE (PHARMA DIVISION) LTD	IT
Lidocaina e Prilocaina Auden 2,5% + 2,5% crema	UK/H/3229/001	043299027	AUDEN MCKENZIE (PHARMA DIVISION) LTD	IT
Lidocaina e Prilocaina Auden 2,5% + 2,5% crema	UK/H/3229/001	043299039	AUDEN MCKENZIE (PHARMA DIVISION) LTD	IT
Lidocaina e Prilocaina Auden 2,5% + 2,5% crema	UK/H/3229/001	043299041	AUDEN MCKENZIE (PHARMA DIVISION) LTD	IT
DENELA 5 %, crème	UK/H/3229/001	NL44263	AUDEN MCKENZIE (PHARMA DIVISION) LTD	FR
Denela 25 mg/g + 25 mg/g Crema	UK/H/3229/001	79196	AUDEN MCKENZIE (PHARMA DIVISION) LTD	UK