



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

1 December 2022
EMA/901823/2022
Human Medicines Evaluation Division

List of nationally authorised medicinal products

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

Procedure no.: PSUSA/00001867/202203

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

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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
Anamap® 25 mg/g + 25 mg/g crema	DK/H/2484/001	83948	GLENMARK ARZNEIMITTEL GMBH	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 Creme	DE/H/2194/001	75572.00.00	PIERRE FABRE DERMO-KOSMETIK GMBH	DE
ANESDERM 25 mg/g + 25 mg/g Creme	DE/H/2194/001	75572.00.00	PIERRE FABRE DERMO-KOSMETIK GMBH	DE
ANESDERM 25 mg/g + 25 mg/g Creme	DE/H/2194/001	75572.00.00	PIERRE FABRE DERMO-KOSMETIK GMBH	DE
ANESDERM 5%, crème	not available	34009 368 636 3 7	PIERRE FABRE DERMATOLOGIE	FR
ANESDERM 5%, crème	not available	34009 382 023 5 9	PIERRE FABRE DERMATOLOGIE	FR
ANESDERM 5%, crème	not available	34009 566 400 6 5	PIERRE FABRE DERMATOLOGIE	FR
Anesderm, (25 mg + 25 mg)/g, krem	DE/H/2194/001	17998	PIERRE FABRE DERMATOLOGIE	PL
Anesderm, (25 mg + 25 mg)/g, krem	DE/H/2194/001	17998	PIERRE FABRE DERMATOLOGIE	PL
Anesderm, (25 mg + 25 mg)/g, krem	DE/H/2194/001	17998	PIERRE FABRE DERMATOLOGIE	PL
Anestderma 25 mg/g + 25 mg/g crema	EE/H/0290/001	84812	GALENICUM DERMA S.L.	ES
ANESTOPIC 25 mg/g + 25 mg/g crema	not available	78664	MESOESTETIC PHARMA GROUP S.L.	ES
ANESTOPIC 25 mg/g + 25 mg/g crema	not available	78664	MESOESTETIC PHARMA GROUP S.L.	ES
Denela 25 mg/g + 25 mg/g kräm	SE/H/1949/001	50703	TEVA B.V	SE
Denela 5% Cream	SE/H/1949/001	PL 00289/2292	TEVA UK LIMITED	XI
EMLA (2,5+2,5)% κρέμα	FI/H/0886/001	16817/16/05-02-2018	ASPEN PHARMA TRADING LIMITED	GR
EMLA 25 mg + 25 mg lääkelastari	not available	11058	ASPEN PHARMA TRADING LIMITED	FI

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EMLA 25 mg + 25 mg medicinskt plåster lidokain, prilokain	not available	11058	ASPEN PHARMA TRADING LIMITED	FI
Emla 25 mg/25 mg medicinskt plåster	not available	11834	ASPEN PHARMA TRADING LIMITED	SE
EMLA 25 mg/25 mg medisineret plaster	not available	8112	ASPEN PHARMA TRADING LIMITED	NO
EMLA 25 mg/g + 25 mg/g crema	FI/H/0886/001	61.096	ASPEN PHARMA TRADING LIMITED	ES
EMLA 25 mg/g + 25 mg/g crema	FI/H/0886/001	027756030	ASPEN PHARMA TRADING LIMITED	IT
EMLA 25 mg/g + 25 mg/g crema	FI/H/0886/001	027756016	ASPEN PHARMA TRADING LIMITED	IT
EMLA 25 mg/g + 25 mg/g crema	FI/H/0886/001	027756028	ASPEN PHARMA TRADING LIMITED	IT
EMLA 25 mg/g + 25 mg/g crema	FI/H/0886/001	027756081	ASPEN PHARMA TRADING LIMITED	IT
EMLA 25 mg/g + 25 mg/g crema	FI/H/0886/001	027756117	ASPEN PHARMA TRADING LIMITED	IT
EMLA 25 mg/g + 25 mg/g crema	FI/H/0886/001	027756105	ASPEN PHARMA TRADING LIMITED	IT
EMLA 25 mg/g + 25 mg/g crema	FI/H/0886/001	027756129	ASPEN PHARMA TRADING LIMITED	IT
EMLA 25 mg/g + 25 mg/g crema	FI/H/0886/001	027756143	ASPEN PHARMA TRADING LIMITED	IT
EMLA 25 mg/g + 25 mg/g crema	FI/H/0886/001	027756156	ASPEN PHARMA TRADING LIMITED	IT
EMLA 25 mg/g + 25 mg/g crema	FI/H/0886/001	027756168	ASPEN PHARMA TRADING LIMITED	IT
EMLA 25 mg/g + 25 mg/g crema	FI/H/0886/001	027756170	ASPEN PHARMA TRADING LIMITED	IT
EMLA 25 mg/g + 25 mg/g Creme	FH/H/0886/001	BE177055	ASPEN PHARMA TRADING LIMITED	BE
EMLA 25 mg/g + 25 mg/g Creme	FI/H/0886/01	2011010957	ASPEN PHARMA TRADING LIMITED	LU
Emla 25 mg/g + 25 mg/g	DK/H/3006/001	2443588	ASPEN PHARMA TRADING	PT

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
creme			LIMITED	
EMLA 25 mg/g + 25 mg/g crème	FI/H/0886/001	2011010957	ASPEN PHARMA TRADING LIMITED	LU
EMLA 25 mg/g + 25 mg/g emulsiovoide	FI_H_0886	9139	ASPEN PHARMA TRADING LIMITED	FI
EMLA 25 mg/g + 25 mg/g kräm	FI/H/0886/001	9139	ASPEN PHARMA TRADING LIMITED	FI
EMLA 25 mg/g + 25 mg/g kräm	FI/H/0886/001	10129	ASPEN PHARMA TRADING LIMITED	SE
Emla 25 mg/g + 25 mg/g krem	FI/H/0886/001	843429	ASPEN PHARMA TRADING LIMITED	IS
Emla 25 mg/g + 25 mg/g krem	FI/H/0886/001	7215	ASPEN PHARMA TRADING LIMITED	NO
EMLA 25 mg/g + 25 mg/g krém	DK/H/3006/001	01/942/97-C	ASPEN PHARMA TRADING LIMITED	CZ
EMLA 5 POUR CENT, crème	FI/H/0886/001	34009 301 424 3 1	ASPEN PHARMA TRADING LIMITED	FR
EMLA 5 POUR CENT, crème	FI/H/0886/001	34009 301 424 5 5	ASPEN PHARMA TRADING LIMITED	FR
EMLA 5 POUR CENT, crème	FI/H/0886/001	34009 550 535 7 6	ASPEN PHARMA TRADING LIMITED	FR
EMLA 5 POUR CENT, crème	FI/H/0886/001	34009 550 535 8 3	ASPEN PHARMA TRADING LIMITED	FR
EMLA 5 POUR CENT, crème	FI/H/0886/001	34009 550 535 9 0	ASPEN PHARMA TRADING LIMITED	FR
Emla 5% - Creme	FI/H/0886/001	1-21507	ASPEN PHARMA TRADING LIMITED	AT
EMLA 5% w/w Cream	FI/H/0886/001	PA 1691/023/001	ASPEN PHARMA TRADING LIMITED	IE
EMLA 5% w/w Cream	FI/H/0886/001	MA955/01001	ASPEN PHARMA TRADING LIMITED	MT
Emla lyfjaplástur	not available	910073	ASPEN PHARMA TRADING LIMITED	IS
EMLA Patch, 25 mg / 25 mg pleister	not available	BE139142	ASPEN PHARMA TRADING LIMITED	BE
EMLA Patch, 25 mg / 25 mg	not available	BE139142	ASPEN PHARMA TRADING	BE

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
wirkstoffhaltiges Pflaster			LIMITED	
EMLA Patch, 25 mg / 25 mg, emplâtre médicamenteux	not available	2011010958	ASPEN PHARMA TRADING LIMITED	LU
EMLA Patch, 25 mg/25 mg, wirkstoffhaltiges Pflaster	not available	2011010958	ASPEN PHARMA TRADING LIMITED	LU
EMLA Patch, 25mg / 25mg emplâtre médicamenteux	not available	BE139142	ASPEN PHARMA TRADING LIMITED	BE
Emla Penso 25 mg/g + 25 mg/g penso impregnado	not available	2426286	ASPEN PHARMA TRADING LIMITED	PT
Emla Penso 25 mg/g + 25 mg/g penso impregnado	not available	2426385	ASPEN PHARMA TRADING LIMITED	PT
EMLA PLASTER, 25 mg + 25 mg, plaster leczniczy	not available	8104	ASPEN PHARMA TRADING LIMITED	PL
EMLA κρέμα 5 %	not available	12900	ASPEN PHARMA TRADING LIMITED	CY
EMLA, 25 mg/g + 25 mg/g, krem	FI/H/0886/001	R/3733	ASPEN PHARMA TRADING LIMITED	PL
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, creme	DK/H/3006/001	11694	ASPEN PHARMA TRADING LIMITED	DK
emla, hydrofiele crème 5%	FI/H/0886/001	RVG 11015	ASPEN PHARMA TRADING LIMITED	NL
Emla, medicinsk plaster	not available	14511	ASPEN PHARMA TRADING LIMITED	DK
Emla, pleister	not available	RVG 15721	ASPEN PHARMA TRADING LIMITED	NL
EMLA® 25 mg/g + 25 mg/g Creme	DK/H/3006/001	42850.00.00	ASPEN PHARMA TRADING LIMITED	DE
EMLA® 5 POUR CENT, crème	FI/H/0886/001	34009 556 938 3 3	ASPEN PHARMA TRADING LIMITED	FR
EMLA® 5 POUR CENT, crème	FI/H/0886/001	34009 556 937 7 2	ASPEN PHARMA TRADING LIMITED	FR
EMLA® 5 POUR CENT, crème	FI/H/0886/001	34009 556 935 4 3	ASPEN PHARMA TRADING	FR

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
			LIMITED	
EMLA® 5 POUR CENT, crème	FI/H/0886/001	34009 559 145 4 9	ASPEN PHARMA TRADING LIMITED	FR
EMLA® 5 POUR CENT, crème	FI/H/0886/001	34009 332 923 2 4	ASPEN PHARMA TRADING LIMITED	FR
EMLA® 5 POUR CENT, crème	FI/H/0886/001	34009 556 936 0 4	ASPEN PHARMA TRADING LIMITED	FR
EMLA® Cream 5%	DK/H/3006/001	PL 39699/0088	ASPEN PHARMA TRADING LIMITED	XI
Emla® Pflaster wirkstoffhaltiges Pflaster Lidocain und Prilocain	not available	1-21505	ASPEN PHARMA TRADING LIMITED	AT
Emla® Pflaster wirkstoffhaltiges Pflaster Lidocain und Prilocain	not available	34386.00.00	ASPEN PHARMA TRADING LIMITED	DE
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
EMLATM Έμπλαστρο φαρμακούχο (2,5 + 2,5) % W/W	not available	78818/16/22-03-17	ASPEN PHARMA TRADING LIMITED	GR
Emulus® 25 mg/g + 25 mg/g Creme	DK/H/2484/001	94455.00.00	HEUMANN PHARMA GMBH & CO. GENERICA KG	DE
Lidocain/Prilocain "IDD", medicinsk plaster	DK/H/3049/001	62229	INTERNATIONAL DRUG DEVELOPMENT	DK
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
Lidocaina/ Prilocaina ratiopharm 25 mg/g + 25	SE/H/1949/001	79196	RATIOPHARM ESPAÑA S.A.,	ES

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mg/g Crema				
Lidocaine/Prilocaine 5 % cutaneous patch	not available	PL 20117/0291	MORNINGSIDE HEALTHCARE LTD	XI
LIDOCAÏNE/PRILOCAÏNE BIO VALYS 5 %, pansement adhésif cutané	DK/H/3049/001/DC	34009 302 090 0 4	INTERNATIONAL DRUG DEVELOPMENT	FR
LIDOCAÏNE/PRILOCAÏNE BIO VALYS 5 %, pansement adhésif cutané	DK/H/3049/001/DC	34009 550 741 2 0	INTERNATIONAL DRUG DEVELOPMENT	FR
LIDOCAÏNE/PRILOCAÏNE BIO VALYS 5 %, pansement adhésif cutané	DK/H/3049/001	34009 302 174 9 8	INTERNATIONAL DRUG DEVELOPMENT	FR
LIDOCAÏNE/PRILOCAÏNE BIO VALYS 5 %, pansement adhésif cutané	DK/H/3049/001	34009 302 175 0 4	INTERNATIONAL DRUG DEVELOPMENT	FR
LIDOCAÏNE/PRILOCAÏNE BIOGARAN 5 %, pansement adhésif cutané	not available	34009 2761097 4	TONIPHARM	FR
LIDOCAÏNE/PRILOCAÏNE BIOGARAN 5 %, pansement adhésif cutané	not available	34009 5857478 8	TONIPHARM	FR
Lidocaine/Prilocaine Teva 25 + 25 mg/g crème	DK/H/2368/001	RVG 115128	TEVA NEDERLAND B.V.	NL
LIDOCAÏNE/PRILOCAÏNE TEVA 5 %, crème	SE/H/1949/001	NL44263	TEVA B.V	FR
LIDOCAÏNE/PRILOCAÏNE ZENTIVA 5 %, pansement adhésif cutané	not available	34009 276 655 1 6	ZENTIVA FRANCE	FR
Lidokain/Prilokain Alternova 25 mg/g + 25 mg/g kräm	DK/H/2484/001	52733	ALTERNOVA A/S	SE
Li-Pri 25 mg/g + 25 mg/g krém	not available	OGYI-T-23417/01	KÉRI PHARMA HUNGARY KFT	HU
Li-Pri 25 mg/g + 25 mg/g krém	not available	OGYI-T-23417/02	KÉRI PHARMA HUNGARY KFT	HU
Li-Pri 25 mg/g + 25 mg/g krém	not available	OGYI-T-23417/03	KÉRI PHARMA HUNGARY KFT	HU

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Li-Pri 25 mg/g + 25 mg/g krém	not available	OGYI-T-23417/04	KÉRI PHARMA HUNGARY KFT	HU
Li-Pri 25 mg/g + 25 mg/g krém	not available	OGYI-T-23417/05	KÉRI PHARMA HUNGARY KFT	HU
Li-Pri 25 mg/g + 25 mg/g krém	not available	OGYI-T-23417/06	KÉRI PHARMA HUNGARY KFT	HU
Lipricain, creme	DK/H/2368/001	53794	TEVA B.V	DK
Motti, 25 mg/g + 25 mg/g, krem	DK/H/2484/001	23504	ZAKLADY FARMACEUTYCZNE "POLPHARMA" SPOLKA AKCYJNA	PL
Nulbia 25 mg/25 mg/g kreem	EE/H/0290/001	983719	NASSINGTON LTD	EE
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	XI
Oraqix 25/25 mg per g Periodontal gel	SE/H/0426/001	PA 1045/4/1	DENTSPLY LIMITED	IE
Oraqix 25/25 mg per g Periodontal gel	SE/H/0426/001	PL 4690/0033	DENTSPLY LIMITED	XI
Oraqix Gel Periodontal	SE/H/0426/001	66719	DENTSPLY DETREY	ES
Oraqix gel periodontale	SE/H/0426/001	037590015	DENTSPLY ITALIA	IT
Oraqix Parodontal-Gel	SE/H/0426/001	59618.00.00	DENTSPLY DETREY	DE
Oraqix periodontalgel	SE/H/0426/001	36518	DENTSPLY DETREY	DK
Oraqix periodontalgel	SE/H/0426/001	04-2648	DENTSPLY DETREY	NO
Oraqix periodontalgel	SE/H/0426/001	18344	DENTSPLY DETREY	SE
Oraqix tannholdshlaup	SE/H/0426/001	IS/1/04/030/01	DENTSPLY DETREY	IS
Oraqix, gel periodontal	SE/H/0426/001	BE288601	DENTSPLY DETREY	BE
Oraqix, gel periodontal	SE/H/0426/001	1538/05025001	DENTSPLY DETREY	LU
ORAQIX, gel périodontal	SE/H/0426/001	34009 367 881 4 5	DENTSPLY SIRONA FRANCE	FR
Oraqix, gel voor peri-odontaal gebruik 25 mg/g + 25 mg/g	SE/H/0426/001	RVG 30847	DENTSPLY DETREY	NL
Oraqix-geeli ientaskuun	SE/H/0426/001	19429	DENTSPLY DETREY	FI
ROMLA 25 mg/25 mg/g cremă	DK/H/2484/001	13998/2021/01	MAGNAPHARM MARKETING & SALES ROMANIA S.R.L.	RO
ROMLA 25 mg/25 mg/g	DK/H/2484/001	13998/2021/02	MAGNAPHARM MARKETING &	RO

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cremă			SALES ROMANIA S.R.L.	
ROMLA 25 mg/25 mg/g cremă	DK/H/2484/001	13998/2021/03	MAGNAPHARM MARKETING & SALES ROMANIA S.R.L.	RO
ROMLA 25 mg/25 mg/g cremă	DK/H/2484/001	13998/2021/04	MAGNAPHARM MARKETING & SALES ROMANIA S.R.L.	RO
ROMLA 25 mg/25 mg/g cremă	DK/H/2484/001	13998/2021/05	MAGNAPHARM MARKETING & SALES ROMANIA S.R.L.	RO
ROMLA 25 mg/25 mg/g cremă	DK/H/2484/001	13998/2021/06	MAGNAPHARM MARKETING & SALES ROMANIA S.R.L.	RO
ROMLA 25mg/25mg/g cream	DK/H/2484/001	2016048	TERIX LABS LTD	BG
ROMLA 25mg/25mg/g cream	DK/H/2484/001	2016048	TERIX LABS LTD	BG
ROMLA 25mg/25mg/g cream	DK/H/2484/001	2016048	TERIX LABS LTD	BG
ROMLA 25mg/25mg/g cream	DK/H/2484/001	2016048	TERIX LABS LTD	BG
ROMLA 25mg/25mg/g cream	DK/H/2484/001	2016048	TERIX LABS LTD	BG
Tapfi 25 mg/25 mg wirkstoffhaltiges Pflaster	DK/H/3049/001	2203804.00.00	PÄDIA GMBH	DE
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 25 mg/25 mg medisiner plaster	DK/H/2316/001	13-9558	ORIFARM GENERICS A/S	NO
Tapin, medicinsk plaster	DK/H/2316/001	52480	ORIFARM GENERICS A/S	DK
РОМЛА 25 mg/25 mg/g крем	DK/H/2484/001	20160418	TERIX LABS LTD	BG