EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 September 2024
EMA/423920/2024
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): amitriptyline, amitriptyline / amitriptylinoxide, amitriptylinoxide

Procedure No. PSUSA/00010374/202401

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

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
Adepril 10 mg compresse rivestite	not available	020019016	TEOFARMA S.R.L.	IT
Adepril 25 mg compresse rivestite	not available	020019028	TEOFARMA S.R.L.	IT
Amineurin 10 mg Filmtabletten	not available	9768.00.00	HEXAL AG	DE
Amineurin 50 mg Filmtabletten	not available	6674129.00.00	HEXAL AG	DE
Amioxid-neuraxpharm 120 mg Tabletten	not available	15844.01.00	NEURAXPHARM ARZNEIMITTEL GMBH	DE
Amioxid-neuraxpharm 30 mg Tabletten	not available	4693.01.00	NEURAXPHARM ARZNEIMITTEL GMBH	DE
Amioxid-neuraxpharm 60 mg Tabletten	not available	4693.02.00	NEURAXPHARM ARZNEIMITTEL GMBH	DE
Amioxid-neuraxpharm 90 mg Tabletten	not available	15844.00.00	NEURAXPHARM ARZNEIMITTEL GMBH	DE
Amitriptylin "Abcur", filmovertrukne tabletter	SE/H/1643/003	58717	ABCUR AB	DK
Amitriptylin ”EQL Pharma”, tabletter, filmovertrukne	not available	06954	EQL PHARMA AB	DK
Amitriptylin ”EQL Pharma”, tabletter, filmovertrukne	not available	06955	EQL PHARMA AB	DK
Amitriptylin ”EQL Pharma”, tabletter, filmovertrukne	not available	06956	EQL PHARMA AB	DK
Amitriptylin Abcur 50 mg filmdragerade tabletter	SE/H/1643/003	34699	ABCUR AB	FI
Amitriptylin Abcur 50 mg filmdrasjerte tabletter	SE/H/1643/003	16-11420	ABCUR AB	NO
Amitriptylin Abcur 50 mg filmuhúðaðar töflur	SE/H/1643/003	IS/1/17/025/03	ABCUR AB	IS
Amitriptylin Abcur 50 mg kalvopäällysteiset tabletit	SE/H/1643/003	34699	ABCUR AB	FI

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Amitriptylin Abcur 50 mg, filmdragerade tabletter	SE/H/1643/003	49701	ABCUR AB	SE
Amitriptylin Micro Labs 10 mg Filmtabletten	NL/H/1967/001	81170.00.00	MICRO LABS GMBH	DE
Amitriptylin Micro Labs 10 mg Filmtabletten	NL/H/1967/001	81170.00.00	MICRO LABS GMBH	DE
Amitriptylin Micro Labs 10 mg Filmtabletten	NL/H/1967/001	81170.00.00	MICRO LABS GMBH	DE
Amitriptylin Micro Labs 10 mg Filmtabletten	NL/H/1967/001	81170.00.00	MICRO LABS GMBH	DE
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Amitriptylin Micro Labs 10 mg Filmtabletten	NL/H/1967/001	81170.00.00	MICRO LABS GMBH	DE
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Amitriptylin Micro Labs 10 mg Filmtabletten	NL/H/1967/001	81170.00.00	MICRO LABS GMBH	DE
Amitriptylin Micro Labs 10 mg Filmtabletten	NL/H/1967/001	81170.00.00	MICRO LABS GMBH	DE
Amitriptylin Micro Labs 10 mg Filmtabletten	NL/H/1967/001	81170.00.00	MICRO LABS GMBH	DE

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Amitriptylin Micro Labs 10 mg Filmtabletten	NL/H/1967/001	81170.00.00	MICRO LABS GMBH	DE
Amitriptylin Micro Labs 10 mg Filmtabletten	NL/H/1967/001	81170.00.00	MICRO LABS GMBH	DE
Amitriptylin Micro Labs 10 mg Filmtabletten	NL/H/1967/001	81170.00.00	MICRO LABS GMBH	DE
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Amitriptylin Micro Labs 10 mg Filmtabletten	NL/H/1967/001	81170.00.00	MICRO LABS GMBH	DE
Amitriptylin Micro Labs 10 mg Filmtabletten	NL/H/1967/001	81170.00.00	MICRO LABS GMBH	DE
Amitriptylin Micro Labs	NL/H/1967/001	81170.00.00	MICRO LABS GMBH	DE

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10 mg Filmtabletten				
Amitriptylin Micro Labs 10 mg Filmtabletten	NL/H/1967/001	81170.00.00	MICRO LABS GMBH	DE
Amitriptylin Micro Labs 10 mg Filmtabletten	NL/H/1967/001	81170.00.00	MICRO LABS GMBH	DE
Amitriptylin Micro Labs 10 mg Filmtabletten	NL/H/1967/001	81170.00.00	MICRO LABS GMBH	DE
Amitriptylin Micro Labs 10 mg Filmtabletten	NL/H/1967/001	81170.00.00	MICRO LABS GMBH	DE
Amitriptylin Micro Labs 66,29 mg Filmtabletten	DE/H/5551/004	2201947.00.00	MICRO LABS GMBH	DE
Amitriptylin Micro Labs 66,29 mg Filmtabletten	DE/H/5551/004	2201947.00.00	MICRO LABS GMBH	DE
Amitriptylin Micro Labs 66,29 mg Filmtabletten	DE/H/5551/004	2201947.00.00	MICRO LABS GMBH	DE
Amitriptylin Micro Labs 66,29 mg Filmtabletten	DE/H/5551/004	2201947.00.00	MICRO LABS GMBH	DE
Amitriptylin Micro Labs 66,29 mg Filmtabletten	DE/H/5551/004	2201947.00.00	MICRO LABS GMBH	DE
Amitriptylin Micro Labs 66,29 mg Filmtabletten	DE/H/5551/004	2201947.00.00	MICRO LABS GMBH	DE
Amitriptylin Micro Labs 66,29 mg Filmtabletten	DE/H/5551/004	2201947.00.00	MICRO LABS GMBH	DE
Amitriptylin Micro Labs 66,29 mg Filmtabletten	DE/H/5551/004	2201947.00.00	MICRO LABS GMBH	DE
Amitriptylin Micro Labs 66,29 mg Filmtabletten	DE/H/5551/004	2020020043	MICRO LABS GMBH	LU
Amitriptylin Micro Labs 66,29 mg Filmtabletten	DE/H/5551/004	2020020043	MICRO LABS GMBH	LU
Amitriptylin Micro Labs 66,29 mg Filmtabletten	DE/H/5551/004	2020020043	MICRO LABS GMBH	LU
Amitriptylin Micro Labs 66,29 mg Filmtabletten	DE/H/5551/004	2020020043	MICRO LABS GMBH	LU
Amitriptylin Micro Labs 66,29 mg Filmtabletten	DE/H/5551/004	2020020043	MICRO LABS GMBH	LU

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Amitriptylin Micro Labs 66,29 mg Filmtabletten	DE/H/5551/004	2020020043	MICRO LABS GMBH	LU
Amitriptylin Micro Labs 66,29 mg Filmtabletten	DE/H/5551/004	2020020043	MICRO LABS GMBH	LU
Amitriptylin Micro Labs 66,29 mg Filmtabletten	DE/H/5551/004	2020020043	MICRO LABS GMBH	LU
Amitriptylin Micro Labs 88,38 mg Filmtabletten	DE/H/5551/005	2201948.00.00	MICRO LABS GMBH	DE
Amitriptylin Micro Labs 88,38 mg Filmtabletten	DE/H/5551/005	2201948.00.00	MICRO LABS GMBH	DE
Amitriptylin Micro Labs 88,38 mg Filmtabletten	DE/H/5551/005	2201948.00.00	MICRO LABS GMBH	DE
Amitriptylin Micro Labs 88,38 mg Filmtabletten	DE/H/5551/005	2201948.00.00	MICRO LABS GMBH	DE
Amitriptylin Micro Labs 88,38 mg Filmtabletten	DE/H/5551/005	2201948.00.00	MICRO LABS GMBH	DE
Amitriptylin Micro Labs 88,38 mg Filmtabletten	DE/H/5551/005	2201948.00.00	MICRO LABS GMBH	DE
Amitriptylin Micro Labs 88,38 mg Filmtabletten	DE/H/5551/005	2201948.00.00	MICRO LABS GMBH	DE
Amitriptylin Micro Labs 88,38 mg Filmtabletten	DE/H/5551/005	2201948.00.00	MICRO LABS GMBH	DE
Amitriptylin Micro Labs 88,38 mg Filmtabletten	DE/H/5551/005	2020020044	MICRO LABS GMBH	LU
Amitriptylin Micro Labs 88,38 mg Filmtabletten	DE/H/5551/005	2020020044	MICRO LABS GMBH	LU
Amitriptylin Micro Labs 88,38 mg Filmtabletten	DE/H/5551/005	2020020044	MICRO LABS GMBH	LU
Amitriptylin Micro Labs 88,38 mg Filmtabletten	DE/H/5551/005	2020020044	MICRO LABS GMBH	LU
Amitriptylin Micro Labs 88,38 mg Filmtabletten	DE/H/5551/005	2020020044	MICRO LABS GMBH	LU
Amitriptylin Micro Labs 88,38 mg Filmtabletten	DE/H/5551/005	2020020044	MICRO LABS GMBH	LU
Amitriptylin Micro Labs	DE/H/5551/005	2020020044	MICRO LABS GMBH	LU

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88,38 mg Filmtabletten				
Amitriptylin Micro Labs 88,38 mg Filmtabletten	DE/H/5551/005	2020020044	MICRO LABS GMBH	LU
Amitriptylin-CT 25 mg Tabletten	not available	6612418.01.00	ABZ-PHARMA GMBH	DE
Amitriptylin-CT 75 mg Tabletten	not available	6612418.00.00	ABZ-PHARMA GMBH	DE
Amitriptyline 10 mg Film-coated Tablets	not available	PL 00289/0178	TEVA UK LIMITED	XI
Amitriptyline 25 mg Film-coated Tablets	not available	PL 00289/0179	TEVA UK LIMITED	XI
Amitriptyline 50 mg Film-coated Tablets	not available	PL 00289/0180	TEVA UK LIMITED	XI
Amitriptyline HCl 10 mg Teva, filmomhulde tabletten	not available	RVG 110148	TEVA NEDERLAND B.V.	NL
Amitriptyline HCl Aurobindo 10 mg, filmomhulde tabletten	not available	RVG 110144	AUROBINDO PHARMA B.V.	NL
Amitriptyline hydrochloride 10mg/5ml Oral Solution	IE/H/0841/001	PA22697/002/001	SYRI PHARMA LIMITED	IE
Amitriptyline hydrochloride 10mg/5ml Oral Solution	UK/H/5514/002	PL 39307/0010	SYRI LIMITED T/A THAME LABORATORIES	XI
Amitriptyline hydrochloride 25mg/5ml Oral Solution	IE/H/0841/002	PA22697/002/002	SYRI PHARMA LIMITED	IE
Amitriptyline hydrochloride 25mg/5ml Oral Solution	UK/H/5514/003	PL 39307/0011	SYRI LIMITED T/A THAME LABORATORIES	XI
Amitriptyline hydrochloride 50mg/5ml Oral Solution	IE/H/0841/003	PA22697/002/003	SYRI PHARMA LIMITED	IE
Amitriptyline	UK/H/5514/004	PL 39307/0012	SYRI LIMITED T/A THAME	XI

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hydrochloride 50mg/5ml Oral Solution			LABORATORIES	
Amitriptylin-neuraxpharm 75 mg Filmtabletten	not available	40687.00.00	NEURAXPHARM ARZNEIMITTEL GMBH	DE
Amitriptylin-neuraxpharm Lösung zum Einnehmen 40 mg/ml	not available	32419.00.00	NEURAXPHARM ARZNEIMITTEL GMBH	DE
Amitriptylin-neuraxpharm Lösung zum Einnehmen 40 mg/ml	not available	32419.00.00	NEURAXPHARM ARZNEIMITTEL GMBH	DE
Amitryptyline HCl 25 mg Teva , filmomhulde tabletten	not available	RVG 110150	TEVA NEDERLAND B.V.	NL
ELAVIL 25 mg, comprimé pelliculé	not available	303 516 3	SUBSTIPHARM	FR
Laroxyl 10 mg compresse rivestite	not available	019906027	TEOFARMA S.R.L.	IT
Laroxyl 25 mg compresse rivestite	not available	019906015	TEOFARMA S.R.L.	IT
LAROXYL 25 mg, comprimé pelliculé	not available	3400955531005	TEOFARMA S.R.L.	FR
Laroxyl 40 mg/ml gocce orali soluzione	not available	019906054	TEOFARMA S.R.L.	IT
Laroxyl 40 mg/mL, solution buvable	not available	305 732-5	TEOFARMA S.R.L.	FR
LAROXYL 50 mg, comprimé pelliculé	not available	3400930573198	TEOFARMA S.R.L.	FR
LAROXYL 50 mg/2 ml, solution injectable	not available	305 729-4	TEOFARMA S.R.L.	FR
Redomex 10 mg comprimés pelliculés	DK/H/2760/001	BE 048736	LUNDBECK SA - N.V.	BE
Redomex 10 mg	DK/H/2760/001	0482/11091255	LUNDBECK SA - N.V.	LU

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comprimés pelliculés				
Redomex 10 mg filmomhulde tabletten	DK/H/2760/001	BE048736	LUNDBECK SA - N.V.	BE
Redomex 10 mg Filmtabletten	DK/H/2760/001	BE048736	LUNDBECK SA - N.V.	BE
Redomex 25 mg comprimés pelliculés	DK/H/2760/002	BE048465	LUNDBECK SA - N.V.	BE
Redomex 25 mg comprimés pelliculés	DK/H/2760/002	0482/11091256	LUNDBECK SA - N.V.	LU
Redomex 25 mg filmomhulde tabletten	DK/H/2760/002	BE048465	LUNDBECK SA - N.V.	BE
Redomex 25 mg Filmtabletten	DK/H/2760/002	BE048465	LUNDBECK SA - N.V.	BE
Redomex Diffucaps 25 mg gélules à libération prolongée	not available	BE048946	LUNDBECK SA, BE	LU
Redomex Diffucaps 50 mg gélules à libération prolongée	not available	BE048937	LUNDBECK SA, BE	LU
Saroten	DK/H/2760/001	10116	H. LUNDBECK A/S	DK
Saroten	DK/H/2760/002	03686	H. LUNDBECK A/S	DK
Saroten 10 mg - Filmtabletten	DK/H/2760/001	11.734	LUNDBECK AUSTRIA GMBH	AT
Saroten 10 mg filmdragerade tabletter	DK/H/2760/001	6833	H. LUNDBECK A/S	SE
Saroten 25 mg - Filmtabletten	DK/H/2760/002	11.735	LUNDBECK AUSTRIA GMBH	AT
Saroten 25 mg filmdragerade tabletter	DK/H/2760/002	6834	H. LUNDBECK A/S	SE
Sarotex 10 mg filmdrasjerte tabletter	DK/H/2760/001	4327	H. LUNDBECK A/S	NO
Sarotex 25 mg filmdrasjerte tabletter	DK/H/2760/002	4328	H. LUNDBECK A/S	NO
TRIPTIZOL 10 mg compresse rivestite	not available	019803028	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	IT

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TRIPTIZOL 25 mg compresse rivestite	not available	019803016	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	IT
TRYPTIZOL 10 mg comprimidos recubiertos con película	not available	51.064	ROVI PHARMA INDUSTRIAL SERVICES S.A.U.	ES
Tryptizol 25 mg comprimidos recubiertos con película	not available	37.130	ROVI PHARMA INDUSTRIAL SERVICES S.A.U.	ES
Tryptizol 50 mg comprimidos recubiertos con película	not available	55.015	ROVI PHARMA INDUSTRIAL SERVICES S.A.U.	ES
Tryptizol 75 mg comprimidos recubiertos con película	not available	55.013	ROVI PHARMA INDUSTRIAL SERVICES S.A.U.	ES