



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

21 September 2021
EMA/617089/2021
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: amitriptyline, amitriptyline / amitriptylinoxide,
amitriptylinoxide

Procedure no.: PSUSA/00010374/202101



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
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", filmovertrokne tablettur	SE/H/1643/003	58717	ABCUR AB	DK
Amitriptylin "Abcur", filmovertrokne tablettur	SE/H/1643/003	58717	ABCUR AB	DK
Amitriptylin Abcur 50 mg filmdragerade tablettur	SE/H/1643/003	34699	ABCUR AB	FI
Amitriptylin Abcur 50 mg filmdragerade tablettur	SE/H/1643/003	34699	ABCUR AB	FI
Amitriptylin Abcur 50 mg filmdrasjerte tablettur	SE/H/1643/003	16-11420	ABCUR AB	NO
Amitriptylin Abcur 50 mg filmdrasjerte tablettur	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 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
Amitriptylin Abcur 50 mg kalvopäällysteiset tabletit	SE/H/1643/003	34699	ABCUR AB	FI

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
Amitriptylin Abcur 50 mg, filmdragerade tabletter	SE/H/1643/003	49701	ABCUR AB	SE
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
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 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 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
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	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 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

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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-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 Tablets	not available	PL 00289/0179	TEVA UK LIMITED	XI
Amitriptyline 50 mg 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 HCl Aurobindo 10 mg, filmomhulde tabletten	not available	RVG 110144	AUROBINDO PHARMA B.V.	NL
Amitriptyline HCl Aurobindo 10 mg, filmomhulde tabletten	not available	RVG 110144	AUROBINDO PHARMA B.V.	NL

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Amitriptyline HCl Aurobindo 10 mg, filmomhulde tabletten	not available	RVG 110144	AUROBINDO PHARMA B.V.	NL
Amitriptyline HCl Aurobindo 10 mg, filmomhulde tabletten	not available	RVG 110144	AUROBINDO PHARMA B.V.	NL
Amitriptyline HCl Mylan 10 mg, filmomhulde tabletten	not available	RVG 110132	MYLAN B.V.	NL
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
Amitriptyline HCl 25 mg Teva , filmomhulde tabletten	not available	RVG 110150	TEVA NEDERLAND B.V.	NL
ELAVIL 25 mg, comprimé pelliculé	not available	V01497-3400930351635	LABORATOIRES GERDA	FR
LAROXYL 25 mg, comprimé pelliculé	not available	3400955531005	TEOFARMA S.R.L.	FR
Laroxyl 40 mg/mL, solution buvable	not available	305 732-5	TEOFARMA S.R.L.	FR
LAROXYL 50 mg, comprimé pelliculé	not available	3400955333913	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	not available	BE048736	LUNDBECK SA - N.V.	LU
Redomex 25 mg comprimés pelliculés	DK/H/2760/002	BE048465	LUNDBECK SA - N.V.	BE

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Redomex 25 mg comprimés pelliculés	not available	BE048465	LUNDBECK SA - N.V.	LU
Redomex 25 mg filmomhulde tabletten	DK/H/2760/002	BE048465	LUNDBECK SA - N.V.	BE
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
Saroten, filmovertrukne tabletter	not available	10116	H. LUNDBECK A/S	DK
Saroten, filmovertrukne tabletter	not available	03686	H. LUNDBECK A/S	DK
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
TRIPTIZOL 10 mg compresse rivestite	not available	019803028	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	IT
TRIPTIZOL 25 mg compresse rivestite	not available	019803016	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	IT
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

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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