



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

21 October 2015
EMA/792231/2015
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: amitriptyline

Procedure no.: PSUSA/00000168/201501



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		020019016	Teofarma S.R.L.	IT
Adepril		020019028	Teofarma S.R.L.	IT
Adt		2468791	Generis Farmacêutica, S.A.	PT
Adt		4510293	Generis Farmacêutica, S.A.	PT
Adt		5003074	Generis Farmacêutica, S.A.	PT
Adt		5003108	Generis Farmacêutica, S.A.	PT
Adt		5003116	Generis Farmacêutica, S.A.	PT
Adt		9076943	Generis Farmacêutica, S.A.	PT
Adt		9076968	Generis Farmacêutica, S.A.	PT
Amirol 10 FC Tablets		7749	Remedica Ltd	CY
Amirol 10 FC Tablets		MA084/02902	Remedica Ltd	MT

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Amirol 25 FC Tablets		7748	Remedica Ltd	CY
Amirol 25 FC Tablets		MA084/02901	Remedica Ltd	MT
Amitriptylin Abcur 10 Mg		49699	Abcur Ab	SE
Amitriptylin Abcur 25 Mg		49700	Abcur Ab	SE
Amitriptylin Abcur 50 Mg		49701	Abcur Ab	SE
Amitriptylin Beta	2132426	32426.00.00	Betapharm Arzneimittel Gmbh	DE
Amitriptylin Beta	2132429	32426.01.00	Betapharm Arzneimittel Gmbh	DE
Amitriptylin Dak		06956	Takeda Pharma A/S	DK
Amitriptylin Dak		6954	Takeda Pharma A/S	DK
Amitriptylin Dak		6955	Takeda Pharma A/S	DK
Amitriptylin Dura		10035.00.00	Mylan Dura Gmbh	DE

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Amitriptylin Dura		10035.02.00	Mylan Dura Gmbh	DE
Amitriptylin Dura		9767.00.00	Mylan Dura Gmbh	DE
Amitriptylin Dura		9767.01.00	Mylan Dura Gmbh	DE
Amitriptylin Micro Labs	NL/H/1967/001	81170.00.00	Micro Labs Gmbh	DE
Amitriptylin Micro Labs	NL/H/1967/002	81171.00.00	Micro Labs Gmbh	DE
Amitriptylin Micro Labs	NL/H/1967/003	81172.00.00	Micro Labs Gmbh	DE
Amitriptylin Slovakofarma		30/0117/95-S	Zentiva, A.S.	SK
Amitriptylin Slovakofarma		30/364/98-C	Zentiva A.S.	CZ
Amitriptyline		PL 00289/0178	Teva Uk Limited Brampton Road, Hampden Park	GB
Amitriptyline		PL 00289/0179	Teva Uk Limited Brampton Road, Hampden Park	GB
Amitriptyline		PL 00289/0180	Teva Uk Limited Brampton Road, Hampden Park	GB

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
Amitriptyline 25mg	PL04556/0039	04556/0039	Pharmvit Limited	GB
Amitriptyline 25mg Tablets		PL 20395/0029	Relon Chem Limited	GB
Amitriptyline Actavis Uk Ltd.	AA702/01801	AA702/01801	Actavis Uk Ltd.	MT
Amitriptyline Actavis Uk Ltd.	AA702/01802	AA702/01802	Actavis Uk Ltd.	MT
Amitriptyline Actavis Uk Ltd.	IS/1/08/103/01	IS/1/08/103/01	Actavis Uk Ltd.	IS
Amitriptyline Actavis Uk Ltd.	IS/1/08/103/02	IS/1/08/103/02	Actavis Uk Ltd.	IS
Amitriptyline Actavis Uk Ltd.	PL 0142/0176	PL 0142/0176	Actavis Uk Ltd.	GB
Amitriptyline Actavis Uk Ltd.	PL 0142/0177	PL 0142/0177	Actavis Uk Ltd.	GB
Amitriptyline Actavis Uk Ltd.	PL 0142/0178	PL 0142/0178	Actavis Uk Ltd.	GB
Amitriptyline Bb	NL/H/1967/001	RVG 107084	Brown & Burk Uk Limited	NL
Amitriptyline Bb	NL/H/1967/002	RVG 107092	Brown & Burk Uk Limited	NL

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Amitriptyline Bb	NL/H/1967/003	RVG 107093	Brown & Burk Uk Limited	NL
Amitriptyline Clonmel Healthcare		PA0126/041/001	Clonmel Healthcare Limited	IE
Amitriptyline Crescent Pharma Limited		PL 20416/0007	Crescent Pharma Limited	GB
Amitriptyline Grindeks		385302	Grindeks	EE
Amitriptyline Grindeks		385402	Grindeks	EE
Amitriptyline Grindeks		99-0092	Grindeks	LV
Amitriptyline Grindeks		99-0474	Grindeks	LV
Amitriptyline Grindeks		LT/1/2000/1331/001	Grindeks	LT
Amitriptyline Grindeks		LT/1/2000/1331/002	Grindeks	LT
Amitriptyline Hci Apotex 10 Mg		RVG 52186	Apotex Europe Bv	NL
Amitriptyline Hci Apotex 25 Mg		RVG 52187	Apotex Europe Bv	NL

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
Amitriptyline Hcl 10 Pch		RVG 21929=52947; RVG 110148, RVG 110150	Pharmachemie B.V. (Teva)	NL
Amitriptyline Hcl 10 Pch		RVG 21929=52947; RVG 110148, RVG 110150	Pharmachemie B.V. (Teva)	NL
Amitriptyline HCl 10mg	n/a	RVG 110144	Actavis B.V.	NL
Amitriptyline HCl 10mg		RVG 110145	Actavis B.V.	NL
Amitriptyline Hcl Cf		RVG 52947	Centrafarm B.V.	NL
Amitriptyline Hcl Cf		RVG 52948	Centrafarm B.V.	NL
Amitriptyline Hcl Ct		6612418.00.00	Abz-Pharma Gmbh, Graf-Arco-Str. 3	DE
Amitriptyline HCL Mylan 10 mg		RVG 110132	Mylan. B.V	NL
Amitriptyline HCL Mylan 25 mg		RVG 110133	Mylan. B.V	NL
Amitriptyline Hcl Sandoz	RVG 110146	RVG 110146	Sandoz B.V.	NL
Amitriptyline Hcl Sandoz	RVG 110147	RVG 110147	Sandoz B.V.	NL

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Amitriptyline HCl Teva 10 mg		RVG 110148	Teva Nederland B.V.	NL
Amitriptyline HCl Teva 25 mg		RVG 110150	Teva Nederland B.V.	NL
amitriptyline hydrochloride 10 mg		06839/1961-0043	Merck Sharp & Dohme BV - Haarlem, NL	SE
amitriptyline hydrochloride 10 mg		06840/1961-0044	Merck Sharp & Dohme BV - Haarlem, NL	SE
amitriptyline hydrochloride 10 mg		08207/1967-0191	Merck Sharp & Dohme BV - Haarlem, NL	SE
Amitriptyline Hydrochloride 10mg/5ml Oral Solution		PL 29831/0460	Wockhardt Uk Ltd	GB
Amitriptyline Hydrochloride Rosemont Pharmaceuticals Ltd		PL 00427/0115	Rosemont Pharmaceuticals Limited	GB
Amitriptyline Hydrochloride Rosemont Pharmaceuticals Ltd		PL 00427/0116	Rosemont Pharmaceuticals Limited	GB
Amitriptyline Hydrochloride Wockhardt Uk Ltd	UK/H/2624/01/DC	29831/0356	Wockhardt Uk Ltd	GB
Amitriptyline Hydrochloride Wockhardt Uk Ltd	UK/H/2624/02/DC	29831/0439	Wockhardt Uk Ltd	GB
Amitriptyline Hydrochloride Wockhardt Uk Ltd	UK/H/2624/02/DC	MA 154/04602	Wockhardt Uk Ltd	MT

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Amitriptyline Hydrochloride Wockhardt Uk Ltd	UK/H/2624/01/DC	MA 154/04601	Wockhardt Uk Ltd	MT
Amitriptyline Metwest Pharmaceuticals Limited		PL 17521/0049	Metwest Pharmaceuticals Limited	GB
Amitriptyline Metwest Pharmaceuticals Limited		PL 17521/0050	Metwest Pharmaceuticals Limited	GB
Amitriptyline Nycomed		232898	Takeda Pharma As	EE
Amitriptyline Nycomed		232998	Takeda Pharma As	EE
Amitriptyline Tablets 10mg		20075/0034	Accord Healthcare Limited	GB
Amitriptyline Tablets 10mg		AA054/03201	Accord Healthcare Limited	MT
Amitriptyline Tablets 25mg		20075/0035	Accord Healthcare Limited	GB
Amitriptyline Tablets 25mg		AA054/03202	Accord Healthcare Limited	MT
Amitriptyline Wockhardt Uk Ltd		29831/0007	Wockhardt Uk Ltd	GB
Amitriptyline Wockhardt Uk Ltd		29831/0008	Wockhardt Uk Ltd	GB

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Amitriptyline Wockhardt Uk Ltd		29831/0009	Wockhardt Uk Ltd	GB
Amitriptyline Wockhardt Uk Ltd		AA154/08801	Wockhardt Uk Ltd	MT
Amitriptyline Wockhardt Uk Ltd		AA154/08802	Wockhardt Uk Ltd	MT
Amitriptylin-neuraxpharm	2132419	32419.00.00	neuraxpharm Arzneimittel GmbH	DE
Amitriptylin-neuraxpharm	2139713	39713.00.00	neuraxpharm Arzneimittel GmbH	DE
Amitriptylin-neuraxpharm 10 mg	0090345	6306905.01.01	neuraxpharm Arzneimittel GmbH	DE
Amitriptylin-neuraxpharm 100 mg	0306905	6306905.00.00	neuraxpharm Arzneimittel GmbH	DE
Amitriptylin-neuraxpharm 25 mg	0090351	6306905.02.01	neuraxpharm Arzneimittel GmbH	DE
Amitriptylin-neuraxpharm 25 mg retard	2143897	43897.00.00	neuraxpharm Arzneimittel GmbH	DE
Amitriptylin-neuraxpharm 50 mg	0068854	6306905.00.01	neuraxpharm Arzneimittel GmbH	DE
Amitriptylin-neuraxpharm 50 mg retard	2143898	43897.01.00	neuraxpharm Arzneimittel GmbH	DE

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Amitriptylin-neuraxpharm 75 mg	2140687	40687.00.00	neuraxpharm Arzneimittel GmbH	DE
Amitriptylin-neuraxpharm 75 mg retard	2143899	43897.02.00	neuraxpharm Arzneimittel GmbH	DE
Amitriptylinum		96-0515	Meda Pharma Sia	LV
Amitriptylinum Vp		10489	Pharmaswiss česká Republika S.R.O.	PL
Amitriptylinum Vp		10490	Pharmaswiss česká Republika S.R.O.	PL
Amitriptylinum Meda		LT/1/94/1987/001	Meda Pharma Sia	LT
Amitriptylinum Meda		LT/1/94/1987/002	Meda Pharma Sia	LT
Amyzol	NOT APPLICABLE	UP/I-530-09/09-02/442	Sandoz D.O.O.	HR
Amyzol	NOT APPLICABLE	UP/I-530-09/09-02/443	Sandoz D.O.O.	HR
Amyzol	NP/H/0144/001	5363-I-667/10	Lek Pharmaceuticals D.D. Ljubljana	SI
Amyzol	NP/H/0144/002	5363-I-688/10	Lek Pharmaceuticals D.D. Ljubljana	SI

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Deprelío		43523	Laboratorio Estedi, S.L.	ES
Elavil		V01497-3400930351635	Laboratoires Gerda	FR
Elavil / Amitriptyline Tablets 10mg		PL 33414/0005	Chelonia Healthcare Limited	GB
Elavil / Amitriptyline Tablets 25mg		PL 33414/0006	Chelonia Healthcare Limited	GB
Laroxyl		019906015	Teofarma S.R.L.	IT
Laroxyl		019906027	Teofarma S.R.L.	IT
Laroxyl		019906054	Teofarma S.R.L.	IT
Laroxyl		305 732-5	Teofarma S.R.L.	FR
Laroxyl		3400930573198	Teofarma S.R.L.	FR
Laroxyl		3400955531005	Teofarma S.R.L.	FR
Laroxyl		V03656	Teofarma S.R.L.	FR

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Ormal		18054	Delorbis Pharmaceuticals Ltd	CY
Ormal		18055	Delorbis Pharmaceuticals Ltd	CY
Ormal		18056	Delorbis Pharmaceuticals Ltd	CY
Psypharm	0306319	6306319.00.00	neuraxpharm Arzneimittel GmbH	DE
Redomex		BE048465	Lundbeck Sa, Be	BE
Redomex		BE048465	Lundbeck Sa, Be	LU
Redomex		BE048736	Lundbeck Sa, Be	BE
Redomex		BE048736	Lundbeck Sa, Be	LU
Redomex Diffucaps		BE048937	Lundbeck Sa, Be	BE
Redomex Diffucaps		BE048937	Lundbeck Sa, Be	LU
Redomex Diffucaps		BE048946	Lundbeck Sa, Be	BE

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Redomex Diffucaps		BE048946	Lundbeck Sa, Be	LU
Saroten		03686	H. Lundbeck A/S	DK
Saroten		10116	H. Lundbeck A/S	DK
Saroten		11.734	Lundbeck Austria Gmbh	AT
Saroten		11.735	Lundbeck Austria Gmbh	AT
Saroten		34530.00.00	Bayer Vital Gmbh	DE
Saroten		45198.00.00	Bayer Vital Gmbh	DE
Saroten		6016478.00.00	Bayer Vital Gmbh	DE
Saroten		6833	H. Lundbeck A/S	SE
Saroten		6834	H. Lundbeck A/S	SE
Saroten Retard		00-0494	H. Lundbeck A/S	LV

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Saroten Retard		06004	H. Lundbeck A/S	DK
Saroten Retard		10115	H. Lundbeck A/S	DK
Saroten Retard		15.089	Lundbeck Austria Gmbh	AT
Saroten Retard		15.984	Lundbeck Austria Gmbh	AT
Saroten Retard		228498	H. Lundbeck A/S	EE
Saroten Retard		5198	C.G.Papaloisou Ltd.	CY
Saroten Retard		5199	C.G.Papaloisou Ltd.	CY
Sarotex		4327	H. Lundbeck A/S	NO
Sarotex		4328	H. Lundbeck A/S	NO
Sarotex Retard		5708	H. Lundbeck A/S	NO
Sarotex Retard		5709	H. Lundbeck A/S	NO

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Sarotex Retard		RVG 06480	Lundbeck B.V., NI	NL
Sarotex Retard		RVG 06481	Lundbeck B.V., NI	NL
Stelminal		37768/2010	COOP ABEE	GR
Stelminal		37764/2010	COOP ABEE	GR
Syneydon 50mg		6068819.00.00	Krewel Meuselbach GmbH	DE
Teperin		OGYI-T-3398	Extractumpharma Co.Ltd.	HU
Triptizol		019803016	Laboratorio Farmaceutico S.I.T. S.R.L.	IT
Triptizol		019803028	Laboratorio Farmaceutico S.I.T. S.R.L.	IT
Triptyl		759	Orion Oyj	FI
Triptyl		759	Orion Oyj	FI
Triptyl		760	Orion Oyj	FI

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Triptyl		760	Orion Oyj	FI
Triptyl		761	Orion Oyj	FI
Triptyl		761	Orion Oyj	FI
Tryptizol		37130	Frosst Ibérica, S.A.	ES
Tryptizol		4538294	Merck Sharp & Dohme, Lda.	PT
Tryptizol		51064	Frosst Ibérica, S.A.	ES
Tryptizol		55013	Frosst Ibérica, S.A.	ES
Tryptizol		55015	Frosst Ibérica, S.A.	ES
Tryptizol		8054247	Merck Sharp & Dohme, Lda.	PT
Tryptizol		8054254	Merck Sharp & Dohme, Lda.	PT
Tryptizol		8054262	Merck Sharp & Dohme, Lda.	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
Tryptizol		8054288	Merck Sharp & Dohme, Lda.	PT