



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

10 September 2015
EMA/701558/2015
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: amisulpride

Procedure no.: PSUSA/00000167/201501



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
Amisulprida Mylan	CZ/H/0211/004	5218755	Mylan Lda	PT
Amisulgen 400mg	CZ/H/0211/004	20090381	Generics [uk] Limited	BG
Amisulprid Mylan	CZ/H/0211/004	5363-I-903/11	Generics [uk] Limited	SI
Amisulprid Mylan	CZ/H/0211/004	68/0531/09-S	Generics [uk] Limited	SK
Amisulprid Mylan 400 mg	CZ/H/0211/004	68/550/09-C	Generics [uk] Limited	CZ
Amisulprida		63.997	Zentiva, K.S.	ES
Amisulprida		63.998	Zentiva, K.S.	ES
Amisulprida		63.999	Zentiva, K.S.	ES
Amisulpride		PL 17780/0012	Winthrop Pharmaceuticals Uk Ltd	GB
Amisulpride		PL 17780/0013	Winthrop Pharmaceuticals Uk Ltd	GB

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Amisulpride		PL 17780/0014	Winthrop Pharmaceuticals Uk Ltd	GB
Amisulpride		PL 17780/0015	Winthrop Pharmaceuticals Uk Ltd	GB
Amisulpride Generics 400mg	CZ/H/0211/004	29111/04-05-2010	Generics Pharma Hellas Ltd	GR
Amisulpride Mylan	CZ/H/0211/004	OGYI-T-21817/10	Generics [uk] Limited	HU
Amisulpride Mylan	CZ/H/0211/004	OGYI-T-21817/11	Generics [uk] Limited	HU
Amisulpride Mylan	CZ/H/0211/004	OGYI-T-21817/12	Generics [uk] Limited	HU
Amisulpride Mylan	CZ/H/0211/004	PA 577/125/004	Mcdermott Laboratories Ltd	IE
Amisulpride Mylan Generics	CZ/H/0211/004	039402161	Mylan S.P.A.	IT
Amisulpride Mylan Generics	CZ/H/0211/004	039402173	Mylan S.P.A.	IT

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Amisulpride Mylan Generics	CZ/H/0211/004	039402185	Mylan S.P.A.	IT
Amisulpridlich		37875.00.00	Winthrop Arzneimittel Gmbh	DE
Amisulpridlich		37875.00.01	Winthrop Arzneimittel Gmbh	DE
Amisulpridlich		37875.01.00	Winthrop Arzneimittel Gmbh	DE
Amisulpridlich		37875.02.00	Winthrop Arzneimittel Gmbh	DE
Amisulpride Mylan 400 mg	CZ/H/0211/004	BE352816	Mylan Bvba/Sprl	BE
Amitrex		1/66/83-1	Sanofi - Produtos Farmaceuticos Lda	PT
Amitrex		1/66/83-2	Sanofi - Produtos Farmaceuticos Lda	PT
Amitrex		99/H/22/001	Sanofi - Produtos Farmaceuticos Lda	PT

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Amitrex		99/H/22/002	Sanofi - Produtos Farmaceuticos Lda	PT
Amitrex	National procedure	OGYI-T-8231/01	Sanofi-Aventis Private Co Ltd	HU
Amitrex	National procedure	OGYI-T-8231/02	Sanofi-Aventis Private Co Ltd	HU
Amitrex	National procedure	OGYI-T-8231/03	Sanofi-Aventis Private Co Ltd	HU
Amitrex	National procedure	OGYI-T-8231/04	Sanofi-Aventis Private Co Ltd	HU
Amitrex	National procedure	OGYI-T-8231/05	Sanofi-Aventis Private Co Ltd	HU
Amitrex	National procedure	OGYI-T-8231/06	Sanofi-Aventis Private Co Ltd	HU
Amitrex	National procedure	OGYI-T-8231/07	Sanofi-Aventis Private Co Ltd	HU
Amitrex	National procedure	OGYI-T-8231/08	Sanofi-Aventis Private Co Ltd	HU

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Amitrex	National procedure	OGYI-T-8231/09	Sanofi-Aventis Private Co Ltd	HU
Amitrex	National procedure	OGYI-T-8231/10	Sanofi-Aventis Private Co Ltd	HU
Deniban		027491012	Sanofi Spa	IT
Deniban		30/013/01-C	sanofi-aventis, s.r.o.	CZ
Misul Amisulprida Mylan Pharmaceuticals 400 mg	CZ/H/0211/004	71542	Mylan Pharmaceuticals S.L.	ES
Socian		1/60/83-1	Sanofi - Produtos Farmaceuticos Lda	PT
Socian		1/60/83-2	Sanofi - Produtos Farmaceuticos Lda	PT
Solian		1-20499	Sanofi-Aventis Gmbh Osterreich	AT
Solian		1-20500	Sanofi-Aventis Gmbh Osterreich	AT

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Solian		1-24890	Sanofi-Aventis Gmbh Osterreich	AT
Solian		1-24891	Sanofi-Aventis Gmbh Osterreich	AT
Solian		NAT/H/4127/005 -5	Sanofi Belgium	BE
Solian		NAT/H/4127/005 -3	Sanofi Belgium	BE
Solian		NAT/H/4127/005 -2	Sanofi Belgium	BE
Solian		NAT/H/4127/005 -4	Sanofi Belgium	BE
Solian		NAT/H/4127/005 -1	Sanofi Belgium	BE
Solian		20010129	Sanofi-Aventis Bulgaria Eood	BG
Solian		19580	Sanofi-Aventis Cyprus Ltd	CY

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Solian		20094	Sanofi-Aventis Cyprus Ltd	CY
Solian		20095	Sanofi-Aventis Cyprus Ltd	CY
Solian		68/459/99-C	sanofi-aventis, s.r.o.	CZ
Solian		37869.00.01	Sanofi-Aventis Deutschland Gmbh	DE
Solian		37869.01.00	Sanofi-Aventis Deutschland Gmbh	DE
Solian		37869.02.00	Sanofi-Aventis Deutschland Gmbh	DE
Solian		48617.00.00	Sanofi-Aventis Deutschland Gmbh	DE
Solian		18669	Sanofi-Aventis Denmark A/S	DK
Solian		18670	Sanofi-Aventis Denmark A/S	DK

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Solian		33699	Sanofi-Aventis Denmark A/S	DK
Solian		324400	Sanofi-Aventis Estonia Oü	EE
Solian		362701	Sanofi-Aventis Estonia Oü	EE
Solian		63.994	Sanofi-Aventis Sa	ES
Solian		63.995	Sanofi-Aventis Sa	ES
Solian		63.996	Sanofi-Aventis Sa	ES
Solian		65.991	Sanofi-Aventis Sa	ES
Solian		NL 24038	Sanofi-Aventis France	FR
Solian		NL 24826	Sanofi-Aventis France	FR

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Solian		NL 13743	Sanofi-Aventis France	FR
Solian		NL 13742	Sanofi-Aventis France	FR
Solian		NL 24037	Sanofi-Aventis France	FR
Solian		NL 13741	Sanofi-Aventis France	FR
Amisulpride Zentiva		NL 28878	Sanofi-Aventis France	FR
Amisulpride Zentiva		NL 28876	Sanofi-Aventis France	FR
Amisulpride Zentiva		NL 30254	Sanofi-Aventis France	FR
Solian		2958/24-01-02	Sanofi-Aventis Aebe	GR
Solian		2959/240-01-02	Sanofi-Aventis Aebe	GR

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Solian		63423/01-12-03	Sanofi-Aventis Aebe	GR
Solian		UP/I-530-09/12-02/453	Sanofi-Aventis Croatia D.O.O.	HR
Solian		PA 540/158/1	Sanofi-Aventis Ireland Ltd	IE
Solian		PA 540/158/3	Sanofi-Aventis Ireland Ltd	IE
Solian		PA 540/158/4	Sanofi-Aventis Ireland Ltd	IE
Solian		990152	Sanofi-Aventis Norge As	IS
Solian		990153	Sanofi-Aventis Norge As	IS
Solian		033462019	Sanofi Spa	IT
Solian		033462021	Sanofi Spa	IT

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
Solian		033462045	Sanofi Spa	IT
Solian		LT/1/98/0282/001	Uab Sanofi-Aventis Lietuva	LT
Solian		LT/1/98/0282/002	Uab Sanofi-Aventis Lietuva	LT
Solian		LT/1/98/0282/004	Uab Sanofi-Aventis Lietuva	LT
Solian		0583/99/07/0001	Sanofi Belgium	LU
Solian		8997	Sanofi Belgium	LU
Solian		8996	Sanofi Belgium	LU
Solian		17057	Sanofi Belgium	LU
Solian		0583/99/07/0002	Sanofi Belgium	LU

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Solian		02-0276	Sanofi-Aventis Latvia Sia	LV
Solian		09-0346	Sanofi-Aventis Latvia Sia	LV
Solian		99-0625	Sanofi-Aventis Latvia Sia	LV
Solian		97-3714	Sanofi-Aventis Norge As	NO
Solian		97-3715	Sanofi-Aventis Norge As	NO
Solian		98-5800	Sanofi-Aventis Norge As	NO
Solian		98-5801	Sanofi-Aventis Norge As	NO
Solian		8408	Sanofi-Aventis France	PL
Solian		8409	Sanofi-Aventis France	PL

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Solian		8410	Sanofi-Aventis France	PL
Solian		5686/2005	Sanofi-Aventis France	RO
Solian		722/2008	Sanofi-Aventis France	RO
Solian		5363-I-305/11	Sanofi-Aventis D.O.O.	SI
Solian		5363-I-306/11	Sanofi-Aventis D.O.O.	SI
Solian		5363-I-307/11	Sanofi-Aventis D.O.O.	SI
Solian		68/0200/00-S	Sanofi-Aventis Slovakia Sro	SK
Solian		68/0201/00-S	Sanofi-Aventis Slovakia Sro	SK
Solian		PL 04425/0651	Aventis Pharma Ltd Uk	GB

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Solian		PL 04425/0652	Aventis Pharma Ltd Uk	GB
Solian		PL 04425/0653	Aventis Pharma Ltd Uk	GB
Solian		68/0202/00-S	Sanofi-Aventis Slovakia Sro	SK
Sulamid		027547013	Laboratori Baldacci Spa	IT