



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 April 2013
EMA/13608/2013 – Rev 1
Patient Health Protection

Annex I

List of the names, pharmaceutical forms, strengths of the medicinal products, routes of administration, marketing authorisation holders in the member states for tetrazepam-containing medicinal product(s)

Article 107i of Directive 2001/83/EC

Procedure number: EMEA/H/A-107i/1352



Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Austria	Sanofi-Aventis GmbH Leonard-Bernstein-Str. 10 Vienna DC A-1220 Vienna Austria	Myolastan 50 mg - Filmtabletten	50 mg	Film-coated tablet	Oral use
Austria	MIP Pharma GmbH Kirkeler Straße 41 D-66440 Blieskastel-Niederwürzbach Germany	Tetrazepam-MIP 50 mg Tabletten	50 mg	Tablet	Oral use
Belgium	Will Pharma S.A. Monplaisirlaan 33 B-1030 Brussel Belgium	Epsipam	50 mg	Film-coated tablet	Oral use
Belgium	Sanofi Aventis Belgium N.V Culliganlaan 1C 1831 Diegem Belgium	Myolastan	50 mg	Film-coated tablet	Oral use
Belgium	Eurogenerics NV Heizel Esplanade b22 1020 Brussel Belgium	Tetrazepam EG	50 mg	Film-coated tablet	Oral use
Bulgaria	Chephasaar Chemisch- Pharmazeutische Fabrik GmbH Mühlstrasse 50 D-66386 Sankt Ingbert Germany	Tetrazepam-MIP	50 mg	Tablet	Oral use
Czech Republic	Sanofi-Aventis, s.r.o. Evropská 846/176a Praha 6 - Vokovice, 160 00 Czech Republic	MYOLASTAN	50 mg	Film-coated tablet	Oral use
France	Sanofi Aventis France 1-13, boulevard Romain Rolland 75014 Paris France	MYOLASTAN 50 mg, comprimé pelliculé sécable	50 mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
France	Daiichi Sankyo France SAS Immeuble le Corosa 1, rue Eugene et Armand Peugeot 92508 Rueil Malmaison France	PANOS 50 mg, comprimé pelliculé sécable	50 mg	Film-coated tablet	Oral use
France	Sandoz 49, avenue Georges Pompidou 92300 Levallois-Perret France	TETRAZEPAM SANDOZ 50 mg, comprimé pelliculé sécable	50 mg	Film-coated tablet	Oral use
France	Zydus France 25, rue des Peupliers ZAC Les Hautes Pâtures - Parc d'Activités des Peupliers 923752 Nanterre France	TETRAZEPAM ZYDUS 50 mg, comprimé enrobé sécable	50 mg	Coated tablet	Oral use
France	Teva Sante 110, Esplanade du Général de Gaulle 92931 Paris La Défense Cedex France	TETRAZEPAM TEVA 50 mg, comprimé pelliculé sécable	50 mg	Film-coated tablet	Oral use
France	Cristers 22 quai Gallieni 92150 Suresnes France	TETRAZEPAM CRISTERS 50 mg, comprimé pelliculé sécable	50 mg	Film-coated tablet	Oral use
France	Ranbaxy Pharmacie Generiques 11-15 Quai Dion Bouton 92816 Puteaux France	TETRAZEPAM RPG 50 mg, comprimé pelliculé sécable	50 mg	Film-coated tablet	Oral use
France	Sanofi Aventis France 1-13, boulevard Romain Rolland 75014 Paris France	TETRAZEPAM ZENTIVA 50 mg, comprimé pelliculé sécable	50 mg	Film-coated tablet	Oral use
France	Mylan SAS 117, allée des Parcs 69800 Saint-Priest France	TETRAZEPAM MYLAN 50 mg, comprimé pelliculé sécable	50 mg	Film-coated tablet	Oral use

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France	EG Labo - Laboratoires Eurogenerics "Le Quintet" - bâtiment A 12, rue Danjou 92517 Boulogne Billancourt Cedex France	TETRAZEPAM EG 50 mg, comprimé pelliculé sécable	50 mg	Film-coated tablet	Oral use
France	ratiopharm GmbH Graf-Arco-Str. 3 89079 Ulm Germany	TETRAZEPAM RATIOPHARM 50 mg, comprimé enrobé sécable	50 mg	Coated tablet	Oral use
France	Arrow Generiques 26, avenue Tony Garnier 69007 Lyon France	TETRAZEPAM ALMUS 50 mg, comprimé pelliculé sécable	50 mg	Film-coated tablet	Oral use
France	Arrow Generiques 26, avenue Tony Garnier 69007 Lyon France	TETRAZEPAM ARROW 50 mg, comprimé pelliculé sécable	50 mg	Film-coated tablet	Oral use
France	Biogaran 15, boulevard Charles de Gaulle 92700 Colombes France	TETRAZEPAM BIOGARAN 50 mg, comprimé pelliculé sécable	50 mg	Film-coated tablet	Oral use
Germany	1 A Pharma GmbH Keltenring 1 + 3 82041 Oberhaching Germany	Tetrazepam - 1 A Pharma	50 mg	Tablet	Oral use
Germany	AbZ-Pharma GmbH Graf-Arco-Str. 3 89079 Ulm Germany	Tetrazepam AbZ 50 mg Filmtabletten	50 mg	Film-coated tablet	Oral use
Germany	Aliud Pharma GmbH Gottlieb-Daimler-Str. 19 89150 Laichingen Germany	Tetrazepam AL 50	50 mg	Tablet	Oral use
Germany	Aristo Pharma GmbH Wallenroder Str. 8-10 13435 Berlin Germany	Spasmorelax 50 mg Tabletten	50 mg	Tablet	Oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Germany	Aristo Pharma GmbH Wallenroder Str. 8-10 13435 Berlin Germany	Tetrazepam-Aristo 50 mg Tabletten	50 mg	Tablet	Oral use
Germany	Chephasaar Chemisch- Pharmazeutische Fabrik GmbH Mühlstrasse 50 D-66386 Sankt Ingbert Germany	Tetra-saar 50mg	50 mg	Tablet	Oral use
Germany	Chephasaar Chemisch- Pharmazeutische Fabrik GmbH Mühlstrasse 50 D-66386 Sankt Ingbert Germany	Tetrazepam-MIP 100 mg Tabletten	100 mg	Tablet	Oral use
Germany	Chephasaar Chemisch- Pharmazeutische Fabrik GmbH Mühlstrasse 50 D-66386 Sankt Ingbert Germany	Tetrazepam-MIP 25 mg Tabletten	25 mg	Tablet	Oral use
Germany	Chephasaar Chemisch- Pharmazeutische Fabrik GmbH Mühlstrasse 50 D-66386 Sankt Ingbert Germany	Tetrazepam-MIP 50 mg Tabletten	50 mg	Tablet	Oral use
Germany	CT Arzneimittel GmbH - Geschäftsanschrift - Graf-Arco-Str. 3 89079 Ulm Germany	Tetrazep-CT 50mg Filmtabletten	50 mg	Film-coated tablet	Oral use
Germany	Hexal Aktiengesellschaft Industriestr. 25 83607 Holzkirchen Germany	Tetrazepam HEXAL	50 mg	Tablet	Oral use
Germany	Krewel Meuselbach GmbH Krewelstr. 2 53783 Eitorf Germany	Musapam	50 mg	Tablet	Oral use

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Germany	KSK-Pharma Vertriebs AG Finkenstr. 1 76327 Pfinztal-Berghausen Germany	Tetrazepam KSK	50 mg	Film-coated tablet	Oral use
Germany	Mylan dura GmbH Wittichstr. 6 64295 Darmstadt Germany	Tetramdura 50mg	50 mg	Film-coated tablet	Oral use
Germany	neuraxpharm Arzneimittel GmbH Elisabeth-Selbert-Str. 23 40764 Langenfeld Germany	Tetrazepam- neuraxpharm 100 mg	100 mg	Tablet	Oral use
Germany	neuraxpharm Arzneimittel GmbH Elisabeth-Selbert-Str. 23 40764 Langenfeld Germany	Tetrazepam- neuraxpharm 50 mg	50 mg	Tablet	Oral use
Germany	ratiopharm GmbH Graf-Arco-Str. 3 89079 Ulm Germany	Tetrazepam- ratiopharm 50 mg Filmtabletten	50 mg	Film-coated tablet	Oral use
Germany	Sandoz Pharmaceuticals GmbH Raiffeisenstr. 11 83607 Holzkirchen Germany	Tetrazepam Sandoz 50mg Tabletten	50 mg	Tablet	Oral use
Germany	Sandoz Pharmaceuticals GmbH Raiffeisenstr. 11 83607 Holzkirchen Germany	Tetrazepam Sandoz 50mg Tabletten	50 mg	Tablet	Oral use
Germany	Sanofi-Aventis Deutschland GmbH Industriepark Höchst, Gebäude K703 65926 Frankfurt am Main Germany	Musaril, 50mg Filmtabletten	50 mg	Film-coated tablet	Oral use
Germany	Stadapharm GmbH Stadastr. 2 - 18 61118 Bad Vilbel Germany	Tetrazepam STADA 50 mg Filmtabletten	50 mg	Film-coated tablet	Oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Latvia	Sanofi – Aventis Latvia SIA Kr. Valdemara str. 33-8 Rīga LV 1010 Latvia	Myolastan 50 mg film-coated tablets	50 mg	Film-coated tablet	Oral use
Lithuania	UAB "Sanofi-Aventis Lietuva" A. Juozapavičiaus g. 6/2 LT-09310 Vilnius Lithuania	Myolastan	50 mg	Film-coated tablet	Oral use
Luxembourg	Will Pharma S.A. Monplaisir laan 33 B-1030 Brussel Belgium	Epsipam	50 mg	Film-coated tablet	Oral use
Luxembourg	Sanofi Aventis Belgium N.V Culliganlaan 1C 1831 Diegem Belgium	Myolastan	50 mg	Film-coated tablet	Oral use
Luxembourg	Eurogenerics NV Heizel Esplanade b22 1020 Brussel Belgium	Tetrazepam EG	50 mg	Film-coated tablet	Oral use
Poland	Przedsiębiorstwo Farmaceutyczne Jelfa S.A. Wincentego st. Pola 21 58-500, Jelenia Góra, Poland	Miozepam	50 mg	Film-coated tablet	Oral use
Poland	Sanofi Aventis France 1-13, boulevard Romain Rolland 75014 Paris France	Myolastan	50 mg	Film-coated tablet	Oral use
Poland	MIP Pharma Polska Sp. z. o.o. ul Orzechowa 5 80-175 Gdansk Poland	Myopam 25	25 mg	Tablet	Oral use
Poland	MIP Pharma Polska Sp. z. o.o. ul Orzechowa 5 80-175 Gdansk Poland	Myopam 50	50 mg	Tablet	Oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Poland	MIP Pharma Polska Sp. z. o.o. ul Orzechowa 5 80-175 Gdansk Poland	Myopam 100	100 mg	Tablet	Oral use
Poland	ratiopharm GmbH Graf-Arco-Str. 3 89079 Ulm Germany	Tetraratio	50 mg	Film-coated tablet	Oral use
Romania	S.C. A.C. Helcor Pharma S.R.L. Str. Victor Babeş nr. 50, Baia Mare Jud. Maramureş România	RELAXAM 50 mg, comprimate filmate	50 mg	Film-coated tablet	Oral use
Slovak Republic	Sanofi-Aventis Slovakia s.r.o. Einsteinova 24 85101 Bratislava Slovak Republic	MYOLASTAN	50 mg	Film-coated tablet	Oral use
Spain	Sanofi Aventis, S.A. Josep Plá, 2 08019 Barcelona Spain	MYOLASTAN 50 mg comprimidos recubiertos	50 mg	Film-coated tablet	Oral use