



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 February 2016
EMA/146245/2016
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: clonazepam

Procedure no.: PSUSA/00000812/201506



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
Aklonil		9040	Medochemie Ltd.	Cyprus
Antelepsin		45191.00.00 \$ 45191.01.00	Desitin Arzneimittel Gmbh	Germany
Clonazepam Auden		PL 17507/0071	Auden Mckenzie (Pharma Division) Ltd	United Kingdom
Clonazepam Auden Mckenzie		PL 17507/0080	Auden Mckenzie (Pharma Division) Ltd	United Kingdom
Clonazepam Lime		OGYI-T-22534/01 \$ OGYI-T-22534/02 \$ OGYI-T-22534/03 \$ OGYI-T-22534/04 \$ OGYI-T-22534/05	Lime Pharma Ltd	Hungary
Clonazepam Lime	UK/H/1890/001	PL 20620/0090	Lime Pharma Ltd	United Kingdom
Clonazepam Lime	UK/H/1890/002	PL 20620/0091	Lime Pharma Ltd	United Kingdom
Clonazepam Neuraxpharm	DE/H/3295/001	84842.00.00	Neuraxpharm Arzneimittel Gmbh	Germany
Clonazepam Olainfarm		03-0054	Jsc Olainfarm	Latvia
Clonazepam Rosemont Pharmaceuticals	UK/H/2487/01/DC \$ UK/H/2487/02/DC	PA 0312/022/002 \$ PA 312/022/001	Rosemont Pharmaceuticals Limited	Ireland
Clonazepam Rosemont Pharmaceuticals	UK/H/2487/01/DC \$ UK/H/2487/02/DC	PL 00427/0157 \$ PL 00427/0158	Rosemont Pharmaceuticals Limited	United Kingdom
Clonazepam Sandoz		RVG 109864	Sandoz B.V.	Netherlands
Clonazepam Sandoz		RVG 109867	Sandoz B.V.	Netherlands
Clonazepam Tiofarma		RVG 106590 \$ RVG 106592	Tiofarma Bv	Netherlands
Clonotril		9144 \$ 9145	Remedica Ltd	Cyprus
Iktorivil		8987	Roche Ab	Sweden
Iktorivil		8988	Roche Ab	Sweden
Iktorivil		9026	Roche Ab	Sweden
Iktorivil		9027	Roche Ab	Sweden
Rivatril		7287	Roche Oy	Finland
Rivatril		7288	Roche Oy	Finland
Rivotril		15.943	Roche Austria Gmbh	Austria

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
Rivotril		15.944	Roche Austria Gmbh	Austria
Rivotril		BE090632	N.V. Roche S.A.	Belgium
Rivotril		BE090641	N.V. Roche S.A.	Belgium
Rivotril		BE090666	N.V. Roche S.A.	Belgium
Rivotril		20000834	Roche Bulgaria Eood	Bulgaria
Rivotril		20000835	Roche Bulgaria Eood	Bulgaria
Rivotril		UP/I-530-09/10-02/453	Roche D.O.O.	Croatia
Rivotril		UP/I-530-09/10-02/454	Roche D.O.O.	Croatia
Rivotril		21/223/73-C	Roche S.R.O.	Czech Republic
Rivotril		21/224/73-C	Roche S.R.O.	Czech Republic
Rivotril		21/225/73-A/C	Roche S.R.O.	Czech Republic
Rivotril		21/225/73-B/C	Roche S.R.O.	Czech Republic
Rivotril		6459	Roche A/S	Denmark
Rivotril		6461	Roche A/S	Denmark
Rivotril		053694	Roche Eesti Oü	Estonia
Rivotril		34009 315 396 8 1	Roche	France
Rivotril		34009 317 050 1 7	Roche	France
Rivotril		34009 317 051 8 5	Roche	France
Rivotril		34009 317 052 4 6	Roche	France
Rivotril		344 282-7	Roche	France
Rivotril		344 283-3	Roche	France
Rivotril		560 469-4	Roche	France
Rivotril		6246267.00.00	Roche Pharma Ag	Germany
Rivotril		6246267.01.00	Roche Pharma Ag	Germany
Rivotril		6246327.00.00	Roche Pharma Ag	Germany
Rivotril		6246327.00.01	Roche Pharma Ag	Germany

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
Rivotril		OGYI-T-1358/01	Roche (Magyarország) Kft	Hungary
Rivotril		OGYI-T-1358/02	Roche (Magyarország) Kft	Hungary
Rivotril		OGYI-T-1358/03	Roche (Magyarország) Kft	Hungary
Rivotril		OGYI-T-1358/04	Roche (Magyarország) Kft	Hungary
Rivotril		751830	Roche A/S	Iceland
Rivotril		920062	Roche A/S	Iceland
Rivotril		PA 50/14/1	Roche Products Ltd	Ireland
Rivotril		PA 50/14/2	Roche Products Ltd	Ireland
Rivotril		023159039	Roche S.P.A.	Italy
Rivotril		023159054	Roche S.P.A.	Italy
Rivotril		023159066	Roche S.P.A.	Italy
Rivotril		LT/1/94/0509/001	Uab "roche Lietuva"	Lithuania
Rivotril		0178/11031000	N.V. Roche S.A.	Luxembourg
Rivotril		0178/11031001	N.V. Roche S.A.	Luxembourg
Rivotril		0178/11031002	N.V. Roche S.A.	Luxembourg
Rivotril		RVG 06870	Roche Nederland B.V.	Netherlands
Rivotril		RVG 06871	Roche Nederland B.V.	Netherlands
Rivotril		RVG 06872	Roche Nederland B.V.	Netherlands
Rivotril		RVG 06873	Roche Nederland B.V.	Netherlands
Rivotril		5976	F. Hoffmann-La Roche Ag	Norway
Rivotril		5977	F. Hoffmann-La Roche Ag	Norway
Rivotril		8414409	Roche Farmacêutica Química, Lda.	Portugal
Rivotril		8414425	Roche Farmacêutica Química, Lda.	Portugal

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
Rivotril		8414458	Roche Farmacêutica Química, Lda.	Portugal
Rivotril		8414508	Roche Farmacêutica Química, Lda.	Portugal
Rivotril		2440/2010/01	Roche Romania Srl	Romania
Rivotril		6229/2014/01	Roche Romania Srl	Romania
Rivotril		21/0223/73-CS	Roche Slovensko S.R.O.	Slovakia
Rivotril		21/0225/73-C/S	Roche Slovensko S.R.O.	Slovakia
Rivotril		21/0225/73-CS	Roche Slovensko S.R.O.	Slovakia
Rivotril		5363-I-1297/09	Roche Farmaceutvska Družba D.O.O.	Slovenia
Rivotril		5363-I-1298/09	Roche Farmaceutvska Družba D.O.O.	Slovenia
Rivotril		52.332	Roche Farma, S.A.	Spain
Rivotril		52.333	Roche Farma, S.A.	Spain
Rivotril		52.334	Roche Farma, S.A.	Spain
Rivotril		52.401	Roche Farma, S.A.	Spain