



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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EMA/112475/2021
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: clonazepam

Procedure no.: PSUSA/00000812/202006

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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 2 mg tablets	not available	9040	MEDOCHEMIE LTD.	CY
Anteplepsin 0,5 mg, Tabletten	not available	45191.00.00	DESITIN ARZNEIMITTEL GMBH	DE
Anteplepsin 2 mg, Tabletten	not available	45191.01.00	DESITIN ARZNEIMITTEL GMBH	DE
Clonazepam Auden 2 mg Tablets	not available	PL 00289/2248	TEVA UK LIMITED	UK
Clonazepam Auden 500 mcg Tablets	not available	PL 00289/2247	TEVA UK LIMITED	UK
Clonazepam Biomed 2mg comprimidos EFG	not available	79769	BIOWISE PHARMACEUTICALS, S.L.	ES
Clonazepam EG 2,5 mg/ml gocce orali soluzione	not available	044150011	EG S.P.A.	IT
Clonazepam Olainfarm 2 mg tabletes	not available	03-0054	JSC OLAINFARM	LV
Clonazepam Rosemont 0.5mg/5ml Oral Solution	UK/H/2487/001	PA 0312/022/001	ROSEMONT PHARMACEUTICALS LIMITED	IE

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
Clonazepam Rosemont 0.5mg/5ml Oral Solution	IE/H/1013/001	PL 00427/0157	ROSEMONT PHARMACEUTICALS LIMITED	UK
Clonazepam Rosemont 2mg/5ml Oral Solution	UK/H/2487/02/DC	PA 0312/022/002	ROSEMONT PHARMACEUTICALS LIMITED	IE
Clonazepam Rosemont 2mg/5ml Oral Solution	IE/H/1013/002	PL 00427/0158	ROSEMONT PHARMACEUTICALS LIMITED	UK
Clonazepam Sandoz 0,5 mg, tabletten	not available	RVG 109864	SANDOZ B.V.	NL
Clonazepam Sandoz 2 mg, tabletten	not available	RVG 109867	SANDOZ B.V.	NL
Clonazepam TioFarma 0,5 mg tabletten, tabletten	not available	RVG 106590	TIOFARMA BV	NL
Clonazepam TioFarma 2 mg tabletten, tabletten	not available	RVG 106592	TIOFARMA BV	NL
Clonazepam Wise 2 mg comprimidos	not available	5674304	WISE PHARMACEUTICALS, UNIPESSOAL, LDA.	PT
Clonazepam-neuraxpharm 2,5 mg/ml Tropfen zum Einnehmen, Lösung	DE/H/3295/001	84842.00.00	NEURAXPHARM ARZNEIMITTEL GMBH	DE

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
CLONAZEPAMUM TZF, 0,5 mg, tabletki	not available	R/1356	TARCHOMIŃSKIE ZAKŁADY FARMACEUTYCZNE "POLFA" SPÓŁKA AKCYJNA	PL
CLONAZEPAMUM TZF, 1 mg/ml, roztwór do wstrzykiwań	not available	R/1664	TARCHOMIŃSKIE ZAKŁADY FARMACEUTYCZNE "POLFA" SPÓŁKA AKCYJNA	PL
CLONAZEPAMUM TZF, 2 mg, tabletki	not available	R/1355	TARCHOMIŃSKIE ZAKŁADY FARMACEUTYCZNE "POLFA" SPÓŁKA AKCYJNA	PL
Clonotril 0.5 mg δισκία	not available	9144	REMEDICA LTD	CY
Clonotril 2 mg δισκία	not available	9145	REMEDICA LTD	CY
Iktorivil 0,5 mg tabletter	not available	8987	ROCHE AB - SOLNA	SE
Iktorivil 2 mg tabletter	not available	8988	ROCHE AB - SOLNA	SE
Rivatril 0,5 mg tablett	not available	7287	ROCHE OY	FI
Rivatril 0,5 mg tabletti	not available	7287	ROCHE OY	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
Rivatriil 2 mg tablett	not available	7288	ROCHE OY	FI
Rivatriil 2 mg tabletti	not available	7288	ROCHE OY	FI
Rivotril "Roche" 0,5 mg - Tabletten	not available	15.943	ROCHE AUSTRIA GMBH	AT
Rivotril "Roche" 2 mg - Tabletten	not available	15.944	ROCHE AUSTRIA GMBH	AT
Rivotril 0,5 mg compresse	not available	023159054	ROCHE S.P.A.	IT
Rivotril 0,5 mg comprimate	not available	6229/2014/01	ROCHE ROMANIA SRL	RO
Rivotril 0,5 mg comprimés	not available	BE090641	N.V. ROCHE S.A.	BE
Rivotril 0,5 mg comprimés	not available	0178/11031002	N.V. ROCHE S.A.	LU
Rivotril 0,5 mg comprimidos	not available	52.334	ROCHE FARMA, S.A.	ES

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 0,5 mg comprimidos	not available	8414409	ROCHE FARMACÊUTICA QUÍMICA, LDA.	PT
Rivotril 0,5 mg comprimidos	not available	8414458	ROCHE FARMACÊUTICA QUÍMICA, LDA.	PT
Rivotril 0,5 mg tablete	not available	HR-H-208455414	ROCHE D.O.O.	HR
Rivotril 0,5 mg tablete	not available	H/96/01366/001	ROCHE FARMACEVTSKA DRUŽBA D.O.O.	SI
Rivotril 0,5 mg tabletta	not available	OGYI-T-1358/01	ROCHE (MAGYARORSZÁG) KFT	HU
Rivotril 0,5 mg tabletten	not available	BE090641	N.V. ROCHE S.A.	BE
Rivotril 0,5 mg Tabletten	not available	BE090641	N.V. ROCHE S.A.	BE
Rivotril 0,5 mg Tabletten	not available	6246267.01.00	ROCHE PHARMA AG	DE
Rivotril 0,5 mg Tabletten	not available	0178/11031002	N.V. ROCHE S.A.	LU

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 0,5 mg tableter	not available	5976	ROCHE NORGE AS, NORWAY	NO
Rivotril 0,5 mg tablety	not available	21/225/73-A/C	ROCHE S. R. O.	CZ
Rivotril 0,5 mg töflur	not available	751830 (IS)	ROCHE A/S	IS
Rivotril 0.5 mg Tablets	not available	PA2307/006/001	ROCHE PRODUCTS (IRELAND) LIMITED	IE
RIVOTRIL 1 mg/1 ml, solution à diluer injectable en ampoules	not available	34009 344 282 7 2	ROCHE	FR
RIVOTRIL 1 mg/1 ml, solution à diluer injectable en ampoules	not available	34009 344 283 3 3	ROCHE	FR
RIVOTRIL 1 mg/1 ml, solution à diluer injectable en ampoules	not available	34009 560 469 4 2	ROCHE	FR
Rivotril 1 mg/ml concentrado y disolvente para solución inyectable	not available	52.332	ROCHE FARMA, S.A.	ES
Rivotril 1 mg/ml koncentrátum és oldószer oldatos injekcióhoz	not available	OGYI-T-1358/04	ROCHE (MAGYARORSZÁG) KFT	HU

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 1 mg/ml Konzentrat zur Herstellung einer Injektionslösung und Lösungsmittel	not available	6246327.00.00	ROCHE PHARMA AG	DE
Rivotril 2 mg compresse	not available	023159066	ROCHE S.P.A.	IT
Rivotril 2 mg comprimate	not available	2440/2010/01	ROCHE ROMANIA SRL	RO
Rivotril 2 mg comprimés	not available	BE090632	N.V. ROCHE S.A.	BE
Rivotril 2 mg comprimés	not available	0178/11031000	N.V. ROCHE S.A.	LU
Rivotril 2 mg comprimidos	not available	52.401	ROCHE FARMA, S.A.	ES
Rivotril 2 mg comprimidos	not available	8414425	ROCHE FARMACÊUTICA QUÍMICA, LDA.	PT
Rivotril 2 mg tablete	not available	HR-H-410362498	ROCHE D.O.O.	HR
Rivotril 2 mg tablete	not available	H/96/01366/002	ROCHE FARMACEVTSKA DRUŽBA D.O.O.	SI

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 2 mg tableta	not available	OGYI-T-1358/02	ROCHE (MAGYARORSZÁG) KFT	HU
Rivotril 2 mg tableta	not available	OGYI-T-1358/03	ROCHE (MAGYARORSZÁG) KFT	HU
Rivotril 2 mg tabletten	not available	BE090632	N.V. ROCHE S.A.	BE
Rivotril 2 mg Tabletten	not available	BE090632	N.V. ROCHE S.A.	BE
Rivotril 2 mg Tabletten	not available	0178/11031000	N.V. ROCHE S.A.	LU
Rivotril 2 mg tabletter	not available	5977	ROCHE NORGE AS, NORWAY	NO
Rivotril 2 mg tablety	not available	21/225/73-B/C	ROCHE S. R. O.	CZ
Rivotril 2 mg töflur	not available	920062 (IS)	ROCHE A/S	IS
Rivotril 2 mg, comprimé quadriséable	not available	34009 381 649 8 5	ROCHE	FR

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 2 mg, comprimé quadrisécable	not available	34009 381 650 6 7	ROCHE	FR
Rivotril 2 mg, comprimé quadrisécable	not available	34009 315 396 8 1	ROCHE	FR
Rivotril 2,5 mg /ml perorální kapky, roztok	not available	21/223/73-C	ROCHE S. R. O.	CZ
Rivotril 2,5 mg/ml druppels voor oraal gebruik, oplossing	not available	BE090666	N.V. ROCHE S.A.	BE
Rivotril 2,5 mg/ml gocce orali soluzione	not available	023159039	ROCHE S.P.A.	IT
Rivotril 2,5 mg/ml gotas orais, solução	not available	8414508	ROCHE FARMACÊUTICA QUÍMICA, LDA.	PT
Rivotril 2,5 mg/ml gotas orales en solución	not available	52.333	ROCHE FARMA, S.A.	ES
Rivotril 2,5 mg/ml solution buvable en gouttes	not available	BE090666	N.V. ROCHE S.A.	BE
Rivotril 2,5 mg/ml solution buvable en gouttes	not available	0178/11031001	N.V. ROCHE S.A.	LU

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 2,5 mg/ml Tropfen zum Einnehmen, Lösung	not available	BE090666	N.V. ROCHE S.A.	BE
Rivotril 2,5 mg/ml Tropfen zum Einnehmen, Lösung	not available	0178/11031001	N.V. ROCHE S.A.	LU
RIVOTRIL 2,5 mg/ml, solution buvable en goutte	not available	34009 317 051 8 5	ROCHE	FR
RIVOTRIL 2,5 mg/ml, solution buvable en goutte	not available	34009 317 050 1 7	ROCHE	FR
RIVOTRIL 2,5 mg/ml, solution buvable en goutte	not available	34009 317 052 4 6	ROCHE	FR
Rivotril concentraat voor oplossing voor injectie, concentraat voor oplossing voor injectie 1 mg/ml	not available	RVG 06873	ROCHE NEDERLAND B.V.	NL
Rivotril druppels, druppels voor oraal gebruik, oplossing 2,5 mg/ml	not available	RVG 06872	ROCHE NEDERLAND B.V.	NL
Rivotril injekční roztok	not available	21/224/73-C	ROCHE S. R. O.	CZ
Rivotril tabletten 0,5 mg , tabletten	not available	RVG 06870	ROCHE NEDERLAND B.V.	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
Rivotril tabletten 2 mg, tabletten	not available	RVG 06871	ROCHE NEDERLAND B.V.	NL
RIVOTRIL, 2 mg tabletid	not available	053694	ROCHE EESTI OÜ	EE
Rivotril, orale dråber, opløsning	not available	06461	ROCHE A/S	DK
Rivotril, tabletter	not available	06459	ROCHE A/S	DK
Rivotril, tabletter	not available	06458	ROCHE A/S	DK
Rivotril® 2 mg Tabletten	not available	6246267.00.00	ROCHE PHARMA AG	DE
Rivotril® 2,5 mg/ml Tropfen zum Einnehmen, Lösung	not available	6246327.00.01	ROCHE PHARMA AG	DE