



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

17 May 2018
EMA/298388/2018
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: midazolam (all pharmaceutical forms and indications apart from oromucosal solution indicated for the treatment of prolonged, acute, convulsive seizures)

Procedure no.: PSUSA/00002057/201709



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
Dormicum 15 mg tabletti, kalvopäällysteinen	not available	9054	ROCHE OY	FI
Dormicum 7,5 mg filmdragerad tablett midazolam	not available	9857	ROCHE OY	FI
Hypnovel 10mg/5ml solution for injection	not available	PA 50/61/2	ROCHE PRODUCTS LTD	IE
Dormicum 15 mg filmom obložene tablete	not available	HR-H-891560860	ROCHE D.O.O.	HR
Dormicum 15 mg/3 ml otopina za injekciju	not available	HR-H-950365768	ROCHE D.O.O.	HR
DORMICUM 5 mg/ml injekční roztok	not available	57/537/92-S/C	ROCHE S.R.O.	CZ
DORMICUM 5 mg/ml injekční roztok	not available	57/537/92-S/C	ROCHE S. R. O.	CZ
Дормикум 5 mg/ml инжекционен разтвор	not available	20030692	ROCHE BULGARIA EOOD	BG
Hypnovel 10 mg/2 ml solution for injection	not available	PL 00031/0126	ROCHE PRODUCTS LTD	UK
Hypnovel 10mg/2ml solution for injection	not available	PA 50/61/1	ROCHE PRODUCTS LTD	IE
Dormicum 7,5 mg Potahované tablety	not available	57/227/89-C	ROCHE S. R. O.	CZ
DORMICUM 5 mg/ml injekční roztok	not available	57/537/92-S/C	ROCHE S. R. O.	CZ
Dormicum 15 mg Potahované tablety	not available	57/538/92-S/C	ROCHE S. R. O.	CZ
Dormicum 7,5 mg filmom obalené tablety	not available	57/0538/92-S	ROCHE SLOVENSKO S.R.O.	SK

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
Dormicum 7,5 mg comprimidos recubiertos con película	not available	59.023	ROCHE FARMA, S.A.	ES
Dormicum 7,5 mg, filmomhulde tabletten	not available	RVG 13027	ROCHE NEDERLAND B.V.	NL
Dormicum 15 mg, filmomhulde tabletten	not available	RVG 10539	ROCHE NEDERLAND B.V.	NL
Dormicum, 7,5 mg, tabletki powlekane	not available	R/0942	ROCHE POLSKA SP.O.O.	PL
Dormicum, 15 mg, tabletki powlekane	not available	R/0943	ROCHE POLSKA SP.O.O.	PL
Dormicum® 7,5 mg Filmtabletten	not available	3430.01.01	ROCHE PHARMA AG	DE
Dormicum 15 mg tabletti, kalvopäällysteinen	not available	9054	ROCHE OY	FI
Dormicum 7,5 mg tabletti, kalvopäällysteinen	not available	9857	ROCHE OY	FI
Dormicum 5 mg/ml injekcinis/infuzinis tirpalas	not available	LT/1/94/0506/002	UAB "ROCHE LIETUVA"	LT
Dormicum 7,5 mg plėvele dengtos tabletės	not available	LT/1/94/0506/001	UAB "ROCHE LIETUVA"	LT
Dormicum 15 mg comprimidos revestidos	not available	8610147	ROCHE FARMACÊUTICA QUÍMICA, LDA.	PT
Dormicum 1 mg/ml raztopina za injiciranje ali infundiranje	not available	H/96/00507/003	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
Dormicum 15 mg filmisko obložene tablete	not available	H/96/00507/002	ROCHE FARMACEVTSKA DRUŽBA D.O.O.	SI
Dormicum 5 mg/ml raztopina za injiciranje ali infundiranje	not available	H/96/00507/004	ROCHE FARMACEVTSKA DRUŽBA D.O.O.	SI
Dormicum 7,5 mg filmisko obložene tablete	not available	H/96/00507/001	ROCHE FARMACEVTSKA DRUŽBA D.O.O.	SI
Dormicum, 7,5 mg õhukese polümeerikattega tabletid	not available	087694	ROCHE EESTI OÜ	EE
Dormicum, 5 mg/ml süste- või infusioonilahus	not available	087594	ROCHE EESTI OÜ	EE
Dormicum 7,5 mg comprimate filmate	not available	4546/2004/01	ROCHE ROMANIA SRL	RO
Dormicum 7,5 mg apvalkotās tabletes	not available	95-0272	ROCHE LATVIJA SIA	LV
Dormicum 5 mg/ml šķīdums injekcijām/infūzijām	not available	95-0271	ROCHE LATVIJA SIA	LV
Midazolam 2mg/ml Solution for Injection/Infusion	not available	PL 02848/0204	MERCURY PHARMA INTERNATIONAL LTD	UK
Midazolam 5mg/ml Solution for Injection/Infusion	not available	PL 02848/0203	MERCURY PHARMA INTERNATIONAL LTD	UK
MIDAZOLAM OVERPHARMA	FR/H/0277/001	5753181	OVERPHARMA - PRODUTOS MÉDICOS E FARMACÊUTICOS, LDA	PT

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MIDAZOLAM OVERPHARMA	FR/H/0277/001	5753082	OVERPHARMA - PRODUTOS MÉDICOS E FARMACÊUTICOS, LDA	PT
MIDAZOLAM OVERPHARMA	FR/H/0277/001	5752985	OVERPHARMA - PRODUTOS MÉDICOS E FARMACÊUTICOS, LDA	PT
MIDAZOLAM OVERPHARMA	FR/H/0277/001	5753280	OVERPHARMA - PRODUTOS MÉDICOS E FARMACÊUTICOS, LDA	PT
Dormicum 5 mg/ml oplossing voor injectie	DE/H/3599/002	RVG 10064	ROCHE NEDERLAND B.V.	NL
Dormicum 5 mg/ml oplossing voor injectie	DE/H/3599/002	RVG 10064	ROCHE NEDERLAND B.V.	NL
Dormicum 15 mg/3 ml stungulyf, lausn	DE/H/3599/002	822969	ROCHE A/S	IS
Dormicum 50 mg/10 ml stungulyf, lausn	DE/H/3599/002	822969	ROCHE A/S	IS
HYPNOVEL 1 mg/ml, solution injectable	DE/H/3599/001	3400955755098	ROCHE	FR
Hypnovel 5 mg/ml, solution injectable	DE/H/3599/002	34009 556 370 7 3	ROCHE	FR
Hypnovel 5 mg/ml, solution injectable	DE/H/3599/002	34009 557 766 1 1	ROCHE	FR
Dormicum 15 mg/3 ml ενέσιμο διάλυμα	DE/H/3599/002	60649/09.09.2010	ROCHE (HELLAS) SA	GR
Dormicum 5 mg/5 ml ενέσιμο διάλυμα	DE/H/3599/001	61090/09.09.2010	ROCHE (HELLAS) SA	GR

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
Dormicum 50 mg/10 ml ενέσιμο διάλυμα	DE/H/3599/002	61092/09.09.2010	ROCHE (HELLAS) SA	GR
Dormicum 1 mg/ml solución inyectable	DE/H/3599/001	60.341	ROCHE FARMA, S.A.	ES
Dormicum 5 mg/ml oplossing voor injectie	DE/H/3599/002	RVG 10064	ROCHE NEDERLAND B.V.	NL
Dormicum® 5 mg/1 ml Injektionslösung	DE/H/3599/002	41119.00.00	ROCHE PHARMA AG	DE
Dormicum® 50 mg/10 ml njektionslösung	DE/H/3599/002	41119.02.00	ROCHE PHARMA AG	DE
DORMICUM "Roche" 5 mg/1 ml – Injektionslösung	DE/H/3599/002	1-18520	ROCHE AUSTRIA GMBH	AT
DORMICUM "Roche" 5 mg/5 ml – Injektionslösung	DE/H/3599/001	1-18809	ROCHE AUSTRIA GMBH	AT
Dormicum® 15 mg/3 ml Injektionslösung	DE/H/3599/002	41119.01.00	ROCHE PHARMA AG	DE
Dormicum® V 5 mg/5 ml Injektionslösung	DE/H/3599/001	41118.00.00	ROCHE PHARMA AG	DE
Dormicum 15 mg/3 ml solução injectável	DE/H/3599/002	8610006	ROCHE FARMACÊUTICA QUÍMICA, LDA.	PT
HYPNOVEL 1 mg/ml, solution injectable	DE/H/3599/001	3400955754909	ROCHE	FR
HYPNOVEL 5 mg/ml, solution injectable	DE/H/3599/002	3400956390663	ROCHE	FR
HYPNOVEL 5 mg/ml, solution injectable	DE/H/3599/002	34009 556 369 9 1	ROCHE	FR

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HYPNOVEL 5 mg/ml, solution injectable	DE/H/3599/002	34009 557 747 7 8	ROCHE	FR
Ipnovel 15 mg/3 ml soluzione iniettabile	DE/H/3599/002	026109049	ROCHE S.P.A.	IT
Ipnovel 5 mg/1 ml soluzione iniettabile	DE/H/3599/002	026109037	ROCHE S.P.A.	IT
Dormicum 5 mg/5 ml stungulyf, lausn	DE/H/3599/001	880086	ROCHE A/S	IS
Dormicum 5 mg/1 ml stungulyf, lausn	DE/H/3599/002	822969	ROCHE A/S	IS
DORMICUM "Roche" 50 mg/10 ml – Injektionslösung	DE/H/3599/002	1-19197	ROCHE AUSTRIA GMBH	AT
MIDAZOLAM OVERPHARMA	FR/H/0277/001	5753181	OVERPHARMA - PRODUTOS MÉDICOS E FARMACÊUTICOS, LDA	PT
MIDAZOLAM OVERPHARMA	FR/H/0277/001	5753082	OVERPHARMA - PRODUTOS MÉDICOS E FARMACÊUTICOS, LDA	PT
MIDAZOLAM OVERPHARMA	FR/H/0277/001	5752985	OVERPHARMA - PRODUTOS MÉDICOS E FARMACÊUTICOS, LDA	PT
MIDAZOLAM OVERPHARMA	FR/H/0277/001	5753280	OVERPHARMA - PRODUTOS MÉDICOS E FARMACÊUTICOS, 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
MIDAZOLAM BIOINDUSTRIA L.I.M. 5 mg/5 ml soluzione iniettabile	not available	039120047	BIOINDUSTRIA LIM LABORATORIO ITALIANO MEDICINALI SPA	IT
Midazolam Sandoz 1 mg/ml oldatos injekció vagy infúzió	NL/H/2461/001	OGYI-T-22381/01	SANDOZ HUNGÁRIA KFT	HU
Midazolam Sandoz 1 mg/ml, oplossing voor injectie of infusie	NL/H/2461/001	RVG 110832	SANDOZ B.V.	NL
Midazolam Sandoz 5 mg/ml, oplossing voor injectie of infusie	NL/H/2461/002	RVG 110837	SANDOZ B.V.	NL
Midazolam Sandoz, 1 mg/ml, roztwór do wstrzykiwań lub infuzji	NL/H/2461/001	20934	SANDOZ GMBH	PL
Midazolam Sandoz, 5 mg/ml, roztwór do wstrzykiwań lub infuzji	NL/H/2461/002	20935	SANDOZ GMBH	PL
Midazolam 2mg/ml Solution for Injection/Infusion	not available	PA 0073/147/002	MERCURY PHARMACEUTICALS (IRELAND) LTD.	IE
Midazolam 5mg/ml Solution for Injection/Infusion	not available	PA 0073/147/001	MERCURY PHARMACEUTICALS (IRELAND) LTD.	IE
Midazolam 1mg/ml Solution for Injection	not available	PL 02848/0207	MERCURY PHARMA INTERNATIONAL LTD	UK