



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

6 September 2018
EMA/382258/2018
Human Medicines Evaluation Division

List of nationally authorised medicinal products for maintenance

Active substance(s): lormetazepam

Procedure No.: PSUSA/00001910/201712



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
Lormetazepam Aurobindo 1 mg, tabletten	not available	RVG 18246	AUROBINDO PHARMA B.V.	NL
Lormetazepam Aurobindo 2 mg, tabletten	not available	RVG 18247	AUROBINDO PHARMA B.V.	NL
Lormetazepam Apotex 2 mg, tabletten	not available	RVG 24658	APOTEX EUROPE B.V.	NL
NOCTAMIDE 2 mg, comprimé sécable	not available	329 869-0	BAYER HEALTHCARE	FR
NOCTAMIDE 1 mg, comprimé sécable	not available	349 667-4	BAYER HEALTHCARE	FR
NOCTAMIDE 1 mg, comprimé sécable	not available	329 868-4	BAYER HEALTHCARE	FR
NOCTAMIDE 2 mg, comprimé sécable	not available	354 470-0	BAYER HEALTHCARE	FR
NOCTAMIDE 2 mg, comprimé sécable	not available	331 476-2	BAYER HEALTHCARE	FR
MINIAS 2,5 mg/mL gocce orali, soluzione	not available	023382029	BAYER SPA	IT
MINIAS 1 mg compresse rivestite	not available	023382017	BAYER SPA	IT
MINIAS 2 mg compresse rivestite	not available	023382031	BAYER SPA	IT
Noctamid Tablets 1 mg	not available	PA 1410/9/1	BAYER LTD	IE
Noctamid Tablets 1 mg	not available	MA639/00301	BAYER LTD	MT
Noctamid®-2 mg, Tablette	not available	3417.02.00	BAYER VITAL GMBH	DE
Noctamid®-1 mg, Tablette	not available	3417.01.00	BAYER VITAL GMBH	DE
Noctamid - Tabletten	not available	17.186	BAYER AUSTRIA GMBH	AT
Pronoctan 1,0 mg tabletter	not available	10325	BAYER AB	DK
Loretam® 2,0 mg Weichkapseln	not available	754.02.02	MEDA PHARMA GMBH & CO. KG	DE
Loretam® 1,0 mg	not available	754.01.02	MEDA PHARMA GMBH & CO.	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
Weichkapseln			KG	
LORAMET 1 mg comprimés	not available	BE 117661	S.A. MEDA PHARMA N.V.	BE
LORAMET 1 mg tabletten	not available	BE 117661	S.A. MEDA PHARMA N.V.	BE
LORAMET 2 mg comprimés	not available	BE 123557	S.A. MEDA PHARMA N.V.	BE
LORAMET 2 mg tabletten	not available	BE 123557	S.A. MEDA PHARMA N.V.	BE
LORAMET 1 mg comprimés	not available	2010/050786	S.A. MEDA PHARMA N.V.	LU
LORAMET 2 mg comprimés	not available	2010/050787	S.A. MEDA PHARMA N.V.	LU
LORAMET 1 mg Tabletten	not available	BE 117661	S.A. MEDA PHARMA N.V.	BE
LORAMET 2 mg Tabletten	not available	BE 123557	S.A. MEDA PHARMA N.V.	BE
LORAMET 1 mg Tabletten	not available	2010/050786	S.A. MEDA PHARMA N.V.	LU
LORAMET 2 mg Tabletten	not available	2010/050787	S.A. MEDA PHARMA N.V.	LU
Loramet 1 mg comprimidos	not available	56.293	MEDA PHARMA S.L.	ES
Loramet 2 mg comprimidos	not available	58.639	MEDA PHARMA S.L.	ES
Lormetazepam Kern Pharma 0,5 mg comprimidos	ES/H/0189/001	75.704	KERN PHARMA, S.L.	ES
Noctamid 1 mg comprimidos	not available	56.296	TEOFARMA S.R.L.	ES
Noctamid 2 mg comprimidos	not available	58.689	TEOFARMA S.R.L.	ES
Noctamid 2,5 mg/ml gotas orales en solución	not available	63.332	TEOFARMA S.R.L.	ES
Ergocalm 1,0 mg Tabletten	not available	754.01.00	TEOFARMA S.R.L.	DE
Ergocalm 2,0 mg Tabletten	not available	754.02.00	TEOFARMA S.R.L.	DE
SEDALAM® 2 mg/10 ml Injektionslösung	not available	74788.00.00	DR. FRANZ KÖHLER CHEMIE GMBH	DE

