



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 September 2015
EMA/739247/2015
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: lormetazepam

Procedure no.: PSUSA/00001910/201412



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
Ergocalm		754.02.00	Teofarma S.R.L.	DE
Loramet		0068/10050786	Meda Pharma s.a. Belgium	LU
Loramet		0068/10050787	Meda Pharma s.a. Belgium	LU
Loramet		56.293	Meda Pharma S.A.U.	ES
Loramet		58.639	Meda Pharma S.A.U.	ES
Loramet		BE 117661	Meda Pharma N.V.	BE
Loramet		BE 123557	Meda Pharma N.V.	BE
Loranka		0160/95/06/0095	Laboratoires Smb S.A.	LU
Loranka		BE166862	Laboratoires Smb S.A.	BE
Loretam		754.01.02	Meda Pharma Gmbh & Co. Kg	DE
Loretam		754.02.02	Meda Pharma Gmbh & Co. Kg	DE
Lormetazepam	ES/H/0189/001/MR	PL 17780/0608-0001	WINTHROP PHARMACEUTICALS UK LIMITED	GB
Lormetazepam Kern Pharma	ES/H/0189/001/MR	75.704	KERN PHARMA, S.L.	ES
Minias		023382017	Bayer Spa	IT
Minias		023382029	Bayer Spa	IT
Minias		023382031	Bayer Spa	IT
Noctamid		17.186	Bayer Austria Gmbh	AT
Noctamid		3417.01.00	Bayer Vital Gmbh	DE
Noctamid		56.296	Bayer Hispania Sl	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
Noctamid		58.689	Bayer Hispania Sl	ES
Noctamid		63.332	Bayer Hispania Sl	ES
Noctamid		MA639/00301	Bayer Ltd	MT
Noctamid		PA 1410/9/1	Bayer Ltd	IE
Noctamid		RVG 08606	Bayer Bv	NL
Noctamid		RVG 15284	Bayer Bv	NL
Noctamid-2mg		3417.02.00	Bayer Vital Gmbh	DE
Noctamide		329 868-4	Bayer Healthcare	FR
Noctamide		329 869-0	Bayer Healthcare	FR
Noctamide		331 476-2	Bayer Healthcare	FR
Noctamide		349 667.4	Bayer Healthcare	FR
Noctamide		354 470.0	Bayer Healthcare	FR
Pronoctan		10325	Bayer Pharma Ag	DK
Sedalam		74788.00.00	Dr. Franz Köhler Chemie Gmbh	DE
Sedador		135508	Dr. Franz Köhler Chemie Gmbh	AT