



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 January 2017
EMA/163329/2017
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance(s): nicardipine

Procedure No.: PSUSA/00002149/201605



Product full name (in authorisation country)	MRP / DCP or CP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
BIONICARD 20 mg Comprime	not available	026071023	ROTTAPHARM S.P.A.	IT
BIONICARD 40 mg capsule rigide a rilascio modificato	not available	026071035	ROTTAPHARM S.P.A.	IT
Cardene 20 mg	not available	PL 00166/0181	ASTELLAS PHARMA LTD.	UK
Cardene 30 mg	not available	PL 00166/0182	ASTELLAS PHARMA LTD.	UK
Cardene IV, 1 mg/ml oplossing voor infusie	NL/H/3207/001	RVG 14835	ASTELLAS PHARMA B.V.	NL
Cardene SR 30	not available	PL 00166/0183	ASTELLAS PHARMA LTD.	UK
Cardene SR 45	not available	RVG 14833	ASTELLAS PHARMA B.V.	NL
Cardene SR 45	not available	PL 00166/0184	ASTELLAS PHARMA LTD.	UK
Flusemide 20 mg comprimidos	not available	56.464	LABORATORIOS Q PHARMA S.L.	ES
Lecibral 20 mg comprimidos	not available	56.481	DESMA LABORATORIO FARMACÉUTICO SL	ES
Lincil 20 mg comprimidos	not available	56370	KERN PHARMA, S.L.	ES
Lincil 30 mg comprimidos	not available	56370	KERN PHARMA, S.L.	ES
Lincil gotas	not available	58311	KERN PHARMA, S.L.	ES
LOXEN 10 mg/10 ml solution injectable (I.V.)	not available	3400933110772	NOVARTIS PHARMA S.A.S.	FR
Loxen 20 mg, comprimé sécable	not available	3400932781737	NOVARTIS PHARMA S.A.S.	FR
Loxen 20 mg, comprimé sécable	not available	3400932781966	NOVARTIS PHARMA S.A.S.	FR
Loxen 20 mg, comprimé sécable	not available	3400932782048	NOVARTIS PHARMA S.A.S.	FR
Loxen 20 mg, comprimé sécable	not available	3400937225670	NOVARTIS PHARMA S.A.S.	FR
LOXEN LP 50 mg, gélule à libération prolongée	not available	3400932955107	NOVARTIS PHARMA S.A.S.	FR
LOXEN LP 50 mg, gélule à libération prolongée	not available	3400937196482	NOVARTIS PHARMA S.A.S.	FR
Nicardipino ratiopharm 20 mg comprimidos	not available	58.447	RATIOPHARM ESPANA SA	ES
Rydene I.V., 1 mg/ml, solution pour perfusion	NL/H/3207/001	BE157421	ASTELLAS PHARMA B.V., OFFICE BE	BE
Rydene I.V., 1 mg/ml, solution pour perfusion	NL/H/3207/001	0566/11010959	ASTELLAS PHARMA B.V., OFFICE BE	LU

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Rydene IV, 1 mg/ml, Lösung zur intravenösen Infusion	NL/H/3207/001	BE157421	ASTELLAS PHARMA B.V., OFFICE BE	BE
Rydene IV, 1 mg/ml, oplossing voor infusie	NL/H/3207/001	BE157421	ASTELLAS PHARMA B.V., OFFICE BE	BE
RYDENE RETARD 45 MG , HARTKAPSELN MIT VERÄNDERTER WIRKSTOFFFREISETZUNG	not available	BE158331	ASTELLAS PHARMA B.V., OFFICE BE	BE
Rydene Retard, 45 mg, gélules à libération modifiée	not available	BE158331	ASTELLAS PHARMA B.V., OFFICE BE	BE
Rydene Retard, 45 mg, gélules à libération modifiée	not available	0566/11010960	ASTELLAS PHARMA B.V., OFFICE BE	LU
Rydene Retard, 45 mg, harde capsules met gereguleerde afgifte	not available	BE158331	ASTELLAS PHARMA B.V., OFFICE BE	BE
VASONASE 1 mg/ml solución para perfusión	NL/H/3207/001	60975	ASTELLAS PHARMA S.A.	ES
VASONASE 30 mg Cápsulas duras	not available	58330	ASTELLAS PHARMA S.A.	ES