



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 January 2020
EMA/34502/2020
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: nicardipine

Procedure no.: PSUSA/00002149/201905



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
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
Flusemide 20 mg comprimidos	not available	56.464	LABORATORIOS Q PHARMA S.L.	ES
Lincil 20 mg comprimidos	not available	56370	KERN PHARMA, S.L.	ES
Lincil 30 mg Comprimidos	not available	59130	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	34009 331 107 7 2	CARDIXO	FR
LOXEN 10 mg / 10 mL, solution injectable (I.V.)	not available	34009 550 632 2 3	CARDIXO	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
LOXEN 20 mg, comprimé sécable	not available	34009 327 817 3 7	CARDIXO	FR
LOXEN 20 mg, comprimé sécable	not available	34009 327 819 6 6	CARDIXO	FR
LOXEN 20 mg, comprimé sécable	not available	34009 327 820 4 8	CARDIXO	FR
LOXEN 20 mg, comprimé sécable	not available	34009 372 256 7 0	CARDIXO	FR
LOXEN LP 50 mg, gélule à libération prolongée	not available	34009 329 551 0 7	CARDIXO	FR
LOXEN LP 50 mg, gélule à libération prolongée	not available	34009 371 964 8 2	CARDIXO	FR
Rydene IV, 1 mg/ml, oplossing voor infusie	NL/H/3207/001	BE157421	ASTELLAS PHARMA B.V., OFFICE BE	BE
Rydene IV, 1 mg/ml, solution pour perfusion	NL/H/3207/001	BE157421	ASTELLAS PHARMA B.V., OFFICE BE	BE
Rydene IV, 1 mg/ml, solution pour perfusion	NL/H/3207/001	2011010959	ASTELLAS PHARMA B.V., OFFICE BE	LU

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Rydene IV, Infusionslösung	NL/H/3207/001	BE157421	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 20 mg Comprimidos recubiertos	not available	56305	ASTELLAS PHARMA S.A.	ES
VASONASE 30 mg Cápsulas duras	not available	58330	ASTELLAS PHARMA S.A.	ES
VASONASE Retard 40 mg Cápsulas duras de liberación modificada	not available	60943	ASTELLAS PHARMA S.A.	ES