



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

2 December 2021
EMA/PRAC/703038/2021
Pharmacovigilance Risk Assessment Committee (PRAC)

List of nationally authorised medicinal products

Active substance(s): nitrendipine

Procedure No.: PSUSA/00002171/202103



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
NIDREL 20 mg, comprimé	not available	34009 330 037 5 3	UCB PHARMA S.A. (COLOMBES FR)	FR
BAYPRESS 20 mg compresse	not available	026232013	BAYER SPA	IT
Lusopress 20 mg tablety	not available	58/1017/97-C	ISTITUTO LUSO FARMACO D'ITALIA S.P.A.	CZ
Baypress 10 mg - Tabletten	not available	1-18429	BAYER AUSTRIA GMBH	AT
Baypress 20 mg - Tabletten	not available	1-18430	BAYER AUSTRIA GMBH	AT
Lusopress®	not available	027254022	ISTITUTO LUSO FARMACO D'ITALIA S.P.A.	IT
Lusopress 20 mg, tablety	not available	58/0469/95-S	ISTITUTO LUSO FARMACO D'ITALIA S.P.A.	SK
Lusopress 20 mg tabletes	not available	97-0654	ISTITUTO LUSO FARMACO D'ITALIA S.P.A.	LV
Lusopress 20 mg tabletid	not available	254499	ISTITUTO LUSO FARMACO D'ITALIA S.P.A.	EE
Lusopress 20 mg tabletės	not available	LT/1/96/2780/001	ISTITUTO LUSO FARMACO D'ITALIA S.P.A.	LT
Tensogradal 20 mg Comprimidos	not available	58.104	KERN PHARMA, S.L.	ES
Bayotensin 20 mg Tabletten	not available	5562.01.00	BAYER VITAL GMBH	DE
Bayotensin® mite, 10 mg, Tabletten	not available	5562.00.00	BAYER VITAL GMBH	DE
Bayotensin akut 5 mg/1 ml Lösung zum Einnehmen	not available	5562.00.01	BAYER VITAL GMBH	DE
NIDREL 20 mg, comprimé	not available	34009 330 037 5 3	UCB PHARMA S.A. (COLOMBES FR)	FR