



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

1 September 2017
EMA/529926/2017
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: amlodipine lisinopril

Procedure no.: PSUSA/00010192/201612



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
Saval 10 mg + 5 mg comprimidos	HU/H/0308/002	5464219	TECNIMEDE - SOCIEDADE TÉCNICO-MEDICINAL, SA	PT
Saval 10 mg + 5 mg comprimidos	HU/H/0308/002	5464227	TECNIMEDE - SOCIEDADE TÉCNICO-MEDICINAL, SA	PT
Saval 10 mg + 5 mg comprimidos	HU/H/0308/002	5464235	TECNIMEDE - SOCIEDADE TÉCNICO-MEDICINAL, SA	PT
Saval 10 mg + 5 mg comprimidos	HU/H/0308/002	5464243	TECNIMEDE - SOCIEDADE TÉCNICO-MEDICINAL, SA	PT
Saval 10 mg + 5 mg comprimidos	HU/H/0308/002	5464250	TECNIMEDE - SOCIEDADE TÉCNICO-MEDICINAL, SA	PT
Saval 10 mg + 5 mg comprimidos	HU/H/0308/002	5464268	TECNIMEDE - SOCIEDADE TÉCNICO-MEDICINAL, SA	PT
Saval 10 mg + 5 mg comprimidos	HU/H/0308/002	5464276	TECNIMEDE - SOCIEDADE TÉCNICO-MEDICINAL, SA	PT
Saval 10 mg + 5 mg comprimidos	HU/H/0308/002	5464300	TECNIMEDE - SOCIEDADE TÉCNICO-MEDICINAL, SA	PT
Saval 20 mg + 5 mg comprimidos	HU/H/0308/001	5453154	TECNIMEDE - SOCIEDADE TÉCNICO-MEDICINAL, SA	PT
Saval 20 mg + 5 mg comprimidos	HU/H/0308/001	5453162	TECNIMEDE - SOCIEDADE TÉCNICO-MEDICINAL, SA	PT

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
Saval 20 mg + 5 mg comprimidos	HU/H/0308/001	5453170	TECNIMEDE - SOCIEDADE TÉCNICO-MEDICINAL, SA	PT
Saval 20 mg + 5 mg comprimidos	HU/H/0308/001	5453204	TECNIMEDE - SOCIEDADE TÉCNICO-MEDICINAL, SA	PT
Saval 20 mg + 5 mg comprimidos	HU/H/0308/001	5453212	TECNIMEDE - SOCIEDADE TÉCNICO-MEDICINAL, SA	PT
Saval 20 mg + 5 mg comprimidos	HU/H/0308/001	5453238	TECNIMEDE - SOCIEDADE TÉCNICO-MEDICINAL, SA	PT
Saval 20 mg + 5 mg comprimidos	HU/H/0308/001	5565015	TECNIMEDE - SOCIEDADE TÉCNICO-MEDICINAL, SA	PT
Saval 20 mg + 5 mg comprimidos	HU/H/0308/001	5565023	TECNIMEDE - SOCIEDADE TÉCNICO-MEDICINAL, SA	PT
Saval 20 mg + 5 mg comprimidos	HU/H/0308/001	5453220	TECNIMEDE - SOCIEDADE TÉCNICO-MEDICINAL, SA	PT
Saval 20 mg + 10 mg comprimidos	HU/H/0308/003	5594601	TECNIMEDE - SOCIEDADE TÉCNICO-MEDICINAL, SA	PT
Saval 20 mg + 10 mg comprimidos	HU/H/0308/003	5594619	TECNIMEDE - SOCIEDADE TÉCNICO-MEDICINAL, SA	PT

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
Saval 20 mg + 10 mg comprimidos	HU/H/0308/003	5594627	TECNIMEDE - SOCIEDADE TÉCNICO-MEDICINAL, SA	PT
Saval 20 mg + 10 mg comprimidos	HU/H/0308/003	5594635	TECNIMEDE - SOCIEDADE TÉCNICO-MEDICINAL, SA	PT
Saval 20 mg + 10 mg comprimidos	HU/H/0308/003	5594643	TECNIMEDE - SOCIEDADE TÉCNICO-MEDICINAL, SA	PT
Saval 20 mg + 10 mg comprimidos	HU/H/0308/003	5594650	TECNIMEDE - SOCIEDADE TÉCNICO-MEDICINAL, SA	PT
Saval 20 mg + 10 mg comprimidos	HU/H/0308/003	5594668	TECNIMEDE - SOCIEDADE TÉCNICO-MEDICINAL, SA	PT
Saval 20 mg + 10 mg comprimidos	HU/H/0308/003	5594676	TECNIMEDE - SOCIEDADE TÉCNICO-MEDICINAL, SA	PT
Normopress 20 mg/5 mg tabletta	HU/H/0307/001	OGYI-T-21585/24	GEDEON RICHTER PLC.	HU
Normopress 20 mg/5 mg tabletta	HU/H/0307/001	OGYI-T-21585/25	GEDEON RICHTER PLC.	HU
Lizam 20 mg/5 mg tabletta	HU/H/0308/001	OGYI-T-21584/24	GEDEON RICHTER PLC.	HU

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
Lizam 20 mg/5 mg tabletta	HU/H/0308/001	OGYI-T-21584/25	GEDEON RICHTER PLC.	HU
Normopress 10 mg/5 mg tabletta	HU/H/0307/002	OGYI-T-21585/01	GEDEON RICHTER PLC.	HU
Lizam Forte 20 mg/10 mg tabletta	HU/H/0308/003	OGYI-T-21584/04	GEDEON RICHTER PLC.	HU
Lizam Forte 20 mg/10 mg tabletta	HU/H/0308/003	OGYI-T-21584/05	GEDEON RICHTER PLC.	HU
Lizam Forte 20 mg/10 mg tabletta	HU/H/0308/003	OGYI-T-21584/06	GEDEON RICHTER PLC.	HU
Lizam Forte 20 mg/10 mg tabletta	HU/H/0308/003	OGYI-T-21584/07	GEDEON RICHTER PLC.	HU
Lizam Forte 20 mg/10 mg tabletta	HU/H/0308/003	OGYI-T-21584/08	GEDEON RICHTER PLC.	HU
Lizam Forte 20 mg/10 mg tabletta	HU/H/0308/003	OGYI-T-21584/09	GEDEON RICHTER PLC.	HU
Normopress Forte 20 mg/10 mg tabletta	HU/H/0307/003	OGYI-T-21585/18	GEDEON RICHTER PLC.	HU

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
Normopress Forte 20 mg/10 mg tabletta	HU/H/0307/003	OGYI-T-21585/19	GEDEON RICHTER PLC.	HU
Normopress Forte 20 mg/10 mg tabletta	HU/H/0307/003	OGYI-T-21585/20	GEDEON RICHTER PLC.	HU
Normopress Forte 20 mg/10 mg tabletta	HU/H/0307/003	OGYI-T-21585/21	GEDEON RICHTER PLC.	HU
Normopress Forte 20 mg/10 mg tabletta	HU/H/0307/003	OGYI-T-21585/22	GEDEON RICHTER PLC.	HU
Normopress Forte 20 mg/10 mg tabletta	HU/H/0307/003	OGYI-T-21585/23	GEDEON RICHTER PLC.	HU
Lizam Forte 20 mg/10 mg tabletta	HU/H/0308/003	OGYI-T-21584/03	GEDEON RICHTER PLC.	HU
Lisonorm Forte 20 mg/10 mg tabletta	HU/H/0133/002	OGYI-T-9684/03	GEDEON RICHTER PLC.	HU
Lizam 10 mg/5 mg tabletta	HU/H/0308/002	OGYI-T-21584/17	GEDEON RICHTER PLC.	HU
Lizam 10 mg/5 mg tabletta	HU/H/0308/002	OGYI-T-21584/18	GEDEON RICHTER PLC.	HU

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
Lizam 10 mg/5 mg tabletta	HU/H/0308/002	OGYI-T-21584/19	GEDEON RICHTER PLC.	HU
Lizam 10 mg/5 mg tabletta	HU/H/0308/002	OGYI-T-21584/20	GEDEON RICHTER PLC.	HU
Lizam 10 mg/5 mg tabletta	HU/H/0308/002	OGYI-T-21584/21	GEDEON RICHTER PLC.	HU
Lizam 10 mg/5 mg tabletta	HU/H/0308/002	OGYI-T-21584/22	GEDEON RICHTER PLC.	HU
Lizam 10 mg/5 mg tabletta	HU/H/0308/002	OGYI-T-21584/23	GEDEON RICHTER PLC.	HU
Lisonorm 10 mg/5 mg, comprimate	HU/H/0133/001	7635/2015/01	GEDEON RICHTER ROMÂNIA S.A.	RO
LISONORM 20 mg/5 mg comprimate	HU/H/0133/003	7637/2015/01	GEDEON RICHTER ROMÂNIA S.A.	RO
LISONORM 20 mg/5 mg comprimate	HU/H/0133/003	7637/2015/02	GEDEON RICHTER ROMÂNIA S.A.	RO
Lisonorm 20 mg/10 mg comprimidos	HU/H/0307/003	703467-4	GEDEON RICHTER PLC.	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
Lisonorm 20 mg/5 mg comprimidos	HU/H/0307/001	712079-7	GEDEON RICHTER PLC.	ES
Lizam 10 mg/5 mg tabletta	HU/H/0308/002	OGYI-T-21584/01	GEDEON RICHTER PLC.	HU
Normopress Forte 20 mg/10 mg tabletta	HU/H/0307/003	OGYI-T-21585/03	GEDEON RICHTER PLC.	HU
Normopress Forte 20 mg/10 mg tabletta	HU/H/0307/003	OGYI-T-21585/02	GEDEON RICHTER PLC.	HU
Диронорм 20 mg/5 mg таблетки	HU/H/0133/003	20120065	GEDEON RICHTER PLC.	BG
Диронорм 10 mg/5 mg таблетки	not available	20060864	GEDEON RICHTER PLC.	BG
Amesos 20 mg/5 mg tablety	HU/H/0133/003	58/085/12-C	GEDEON RICHTER PLC.	CZ
Dironorm 10 mg/5 mg tabletes	HU/H/0133/001	09-0036	GEDEON RICHTER PLC.	LV
DIRONORM 10 mg/5 mg tabletės	HU/H/0133/001	LT/1/09/1442/001	GEDEON RICHTER PLC.	LT

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
Dironorm, 10 mg + 5 mg, tabletki	HU/H/0133/001	15436	GEDEON RICHTER POLSKA SP. Z. O.O.	PL
Lizam Forte 20 mg/10 mg tableta	HU/H/0308/003	OGYI-T-21584/02	GEDEON RICHTER PLC.	HU
Amesos 20 mg/10 mg tablety	HU/H/0133/002	58/772/09-C	GEDEON RICHTER PLC.	CZ
Amesos 10 mg/5 mg tablety	HU/H/0133/001	58/238/09-C	GEDEON RICHTER PLC.	CZ
Lisonorm 10 mg/5 mg tableta	HU/H/0133/001	OGYI-T-9684/01	GEDEON RICHTER PLC.	HU
Lisonorm Forte 20 mg/10 mg tableta	HU/H/0133/002	OGYI-T-9684/02	GEDEON RICHTER PLC.	HU
Диронорм 20 mg/10 mg таблетки	not available	20110318	GEDEON RICHTER PLC.	BG
DIRONORM 20 mg/10 mg tabletės	HU/H/0133/002	LT/1/09/1442/003	GEDEON RICHTER PLC.	LT
Dironorm 20 mg/10 mg tabletes	HU/H/0133/002	09-0465	GEDEON RICHTER PLC.	LV

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
DIRONORM 20 mg/10 mg tabletés	HU/H/0133/002	LT/1/09/1442/002	GEDEON RICHTER PLC.	LT
Dironorm 10 mg/5 mg tablety	HU/H/0133/001	58/0431/08-S	GEDEON RICHTER PLC.	SK
Dironorm Forte 20 mg/10 mg tablety	HU/H/0133/002	58/0536/09-S	GEDEON RICHTER PLC.	SK
Dironorm, 20 mg + 10 mg, tabletki	HU/H/0133/002	16394	GEDEON RICHTER POLSKA SP. Z. O.O.	PL
Dironorm 10 mg /5 mg tabletid	HU/H/0133/001	616709	GEDEON RICHTER PLC.	EE
Dironorm 20 mg/5 mg tabletes	HU/H/0133/003	12-0105	GEDEON RICHTER PLC.	LV
Lizam 20 mg/5 mg comprimés	HU/H/0308/001	2012050039	GEDEON RICHTER PLC.	LU
Dironorm, 20 mg + 5 mg, tabletki	HU/H/0133/003	20093	GEDEON RICHTER POLSKA SP. Z. O.O.	PL
DIRONORM 20 mg/5 mg tabletés	HU/H/0133/003	LT/1/09/1442/004	GEDEON RICHTER PLC.	LT

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
DIRONORM 20 mg/5 mg tabletès	HU/H/0133/003	LT/1/09/1442/005	GEDEON RICHTER PLC.	LT
Lisonorm 20 mg/5 mg tabletta	HU/H/0133/003	OGYI-T-9684/05	GEDEON RICHTER PLC.	HU
Lisonorm 20 mg/5 mg tabletta	HU/H/0133/003	OGYI-T-9684/04	GEDEON RICHTER PLC.	HU
DIRONORM 20 mg/5 mg tabletid	HU/H/0133/003	780112	GEDEON RICHTER PLC.	EE
Lizam 20 mg/5 mg tabletta	HU/H/0308/001	OGYI-T-21584/10	GEDEON RICHTER PLC.	HU
Lizam 20 mg/5 mg tabletta	HU/H/0308/001	OGYI-T-21584/11	GEDEON RICHTER PLC.	HU
Lizam 20 mg/5 mg tabletta	HU/H/0308/001	OGYI-T-21584/12	GEDEON RICHTER PLC.	HU
Lizam 20 mg/5 mg tabletta	HU/H/0308/001	OGYI-T-21584/13	GEDEON RICHTER PLC.	HU
Lizam 20 mg/5 mg tabletta	HU/H/0308/001	OGYI-T-21584/14	GEDEON RICHTER PLC.	HU

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
Lizam 20 mg/5 mg tabletta	HU/H/0308/001	OGYI-T-21584/15	GEDEON RICHTER PLC.	HU
Lizam 20 mg/5 mg tabletta	HU/H/0308/001	OGYI-T-21584/16	GEDEON RICHTER PLC.	HU
Normopress 20 mg/5 mg tabletta	HU/H/0307/001	OGYI-T-21585/04	GEDEON RICHTER PLC.	HU
Normopress 20 mg/5 mg tabletta	HU/H/0307/001	OGYI-T-21585/05	GEDEON RICHTER PLC.	HU
Normopress 20 mg/5 mg tabletta	HU/H/0307001	OGYI-T-21585/06	GEDEON RICHTER PLC.	HU
Normopress 20 mg/5 mg tabletta	HU/H/0307/001	OGYI-T-21585/07	GEDEON RICHTER PLC.	HU
Normopress 20 mg/5 mg tabletta	HU/H/0307/001	OGYI-T-21585/08	GEDEON RICHTER PLC.	HU
Normopress 20 mg/5 mg tabletta	HU/H/0307/001	OGYI-T-21585/09	GEDEON RICHTER PLC.	HU
Normopress 20 mg/5 mg tabletta	HU/H/0307/001	OGYI-T-21585/10	GEDEON RICHTER PLC.	HU

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
Normopress 10 mg/5 mg tabletta	HU/H/0307/002	OGYI-T-21585/11	GEDEON RICHTER PLC.	HU
Normopress 10 mg/5 mg tabletta	HU/H/0307/002	OGYI-T-21585/12	GEDEON RICHTER PLC.	HU
Normopress 10 mg/5 mg tabletta	HU/H/0307/002	OGYI-T-21585/13	GEDEON RICHTER PLC.	HU
Normopress 10 mg/5 mg tabletta	HU/H/0307/002	OGYI-T-21585/14	GEDEON RICHTER PLC.	HU
Normopress 10 mg/5 mg tabletta	HU/H/0307/002	OGYI-T-21585/15	GEDEON RICHTER PLC.	HU
Normopress 10 mg/5 mg tabletta	HU/H/0307/002	OGYI-T-21585/16	GEDEON RICHTER PLC.	HU
Normopress 10 mg/5 mg tabletta	HU/H/0307/002	OGYI-T-21585/17	GEDEON RICHTER PLC.	HU
Lizam 20 mg/10 mg comprimés	HU/H/0308/003	2013060187	GEDEON RICHTER PLC.	LU
Lisonorm 10 mg + 5 mg comprimidos	HU/H/0307/002	5464110	LUSOMEDICAMENTA – SOCIEDADE TÉCNICA FARMACÊUTICA, SA	PT

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
Lisonorm 10 mg + 5 mg comprimidos	HU/H/0307/002	5464128	LUSOMEDICAMENTA – SOCIEDADE TÉCNICA FARMACÊUTICA, SA	PT
Lisonorm 10 mg + 5 mg comprimidos	HU/H/0307/002	5464136	LUSOMEDICAMENTA – SOCIEDADE TÉCNICA FARMACÊUTICA, SA	PT
Lisonorm 10 mg + 5 mg comprimidos	HU/H/0307/002	5464144	LUSOMEDICAMENTA – SOCIEDADE TÉCNICA FARMACÊUTICA, SA	PT
Lisonorm 10 mg + 5 mg comprimidos	HU/H/0307/002	5464151	LUSOMEDICAMENTA – SOCIEDADE TÉCNICA FARMACÊUTICA, SA	PT
Lisonorm 10 mg + 5 mg comprimidos	HU/H/0307/002	5464169	LUSOMEDICAMENTA – SOCIEDADE TÉCNICA FARMACÊUTICA, SA	PT
Lisonorm 10 mg + 5 mg comprimidos	HU/H/0307/002	5464177	LUSOMEDICAMENTA – SOCIEDADE TÉCNICA FARMACÊUTICA, SA	PT
Lisonorm 10 mg + 5 mg comprimidos	HU/H/0307/002	5464201	LUSOMEDICAMENTA – SOCIEDADE TÉCNICA FARMACÊUTICA, SA	PT
Lisonorm 20 mg + 10 mg comprimidos	HU/H/0307/003	5594502	LUSOMEDICAMENTA – SOCIEDADE TÉCNICA FARMACÊUTICA, SA	PT
Lisonorm 20 mg + 10 mg comprimidos	HU/H/0307/003	5594510	LUSOMEDICAMENTA – SOCIEDADE TÉCNICA FARMACÊUTICA, SA	PT

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
Lisonorm 20 mg + 10 mg comprimidos	HU/H/0307/003	5594551	LUSOMEDICAMENTA – SOCIEDADE TÉCNICA FARMACÊUTICA, SA	PT
Lisonorm 20 mg + 10 mg comprimidos	HU/H/0307/003	5594536	LUSOMEDICAMENTA – SOCIEDADE TÉCNICA FARMACÊUTICA, SA	PT
Lisonorm 20 mg + 10 mg comprimidos	HU/H/0307/003	5594569	LUSOMEDICAMENTA – SOCIEDADE TÉCNICA FARMACÊUTICA, SA	PT
Lisonorm 20 mg + 10 mg comprimidos	HU/H/0307/003	5594528	LUSOMEDICAMENTA – SOCIEDADE TÉCNICA FARMACÊUTICA, SA	PT
Lisonorm 20 mg + 10 mg comprimidos	HU/H/0307/003	5594544	LUSOMEDICAMENTA – SOCIEDADE TÉCNICA FARMACÊUTICA, SA	PT
Lisonorm 20 mg + 10 mg comprimidos	HU/H/0307/003	5594577	LUSOMEDICAMENTA – SOCIEDADE TÉCNICA FARMACÊUTICA, SA	PT
Lisonorm 20 mg + 5 mg comprimidos	HU/H/0307/001	5453063	LUSOMEDICAMENTA – SOCIEDADE TÉCNICA FARMACÊUTICA, SA	PT
Lisonorm 20 mg + 5 mg comprimidos	HU/H/0307/001	5453071	LUSOMEDICAMENTA – SOCIEDADE TÉCNICA FARMACÊUTICA, SA	PT
Lisonorm 20 mg + 5 mg comprimidos	HU/H/0307/001	5453105	LUSOMEDICAMENTA – SOCIEDADE TÉCNICA FARMACÊUTICA, SA	PT

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
Lisonorm 20 mg + 5 mg comprimidos	HU/H/0307/001	5453113	LUSOMEDICAMENTA – SOCIEDADE TÉCNICA FARMACÊUTICA, SA	PT
Lisonorm 20 mg + 5 mg comprimidos	HU/H/0307/001	5453121	LUSOMEDICAMENTA – SOCIEDADE TÉCNICA FARMACÊUTICA, SA	PT
Lisonorm 20 mg + 5 mg comprimidos	HU/H/0307/001	5453139	LUSOMEDICAMENTA – SOCIEDADE TÉCNICA FARMACÊUTICA, SA	PT
Lisonorm 20 mg + 5 mg comprimidos	HU/H/0307/001	5453147	LUSOMEDICAMENTA – SOCIEDADE TÉCNICA FARMACÊUTICA, SA	PT
Lisonorm 20 mg + 5 mg comprimidos	HU/H/0307/001	5565007	LUSOMEDICAMENTA – SOCIEDADE TÉCNICA FARMACÊUTICA, SA	PT
Lisonorm 20 mg + 5 mg comprimidos	HU/H/0307/001	5564976	LUSOMEDICAMENTA – SOCIEDADE TÉCNICA FARMACÊUTICA, SA	PT
LISAM 20 mg/5 mg Tabletten	HU/H/0307/001	1-31502	+PHARMA ARZNEIMITTEL GMBH	AT
LISAM 10 mg/5 mg Tabletten	HU/H/0308/002	1-31503	+PHARMA ARZNEIMITTEL GMBH	AT
LISAM 20 mg/10 mg Tabletten	HU/H/0308/003	1-31885	+PHARMA ARZNEIMITTEL GMBH	AT