



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 February 2026
EMADOC-1700519818-2916886
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): amlodipine/irbesartan

EURD list No. PSUSA/00010876/202506

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

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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
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
Aproxxamlo	ES/H/0594/003	94603/22-09-2020	Sanofi-Aventis Monoprosopi A.E.B.E	Hellenic Republic
Combipress	CY/H/0154/001		Win Medica Pharmaceutical S.A.	Hellenic Republic
Combipress	CY/H/0154/002	023514	Win Medica Pharmaceutical S.A.	Republic of Cyprus
EBIMIA		55600/17-06-2021	Elpen Pharmaceutical Co. Inc.	Hellenic Republic
Aproxxamlo	ES/H/0594/004	94604/22-09-2020	Sanofi-Aventis Monoprosopi A.E.B.E	Hellenic Republic
Aproxxamlo	ES/H/0594/001	94601/22-09-2020	Sanofi-Aventis Monoprosopi A.E.B.E	Hellenic Republic
Aproxxamlo	ES/H/0594/001	94601/22-09-2020	Sanofi-Aventis Monoprosopi A.E.B.E	Hellenic Republic
EBIMIA		55598/17-06-2021	Elpen Pharmaceutical Co. Inc.	Hellenic Republic
Aproxxamlo	ES/H/0594/002	85200	Sanofi Aventis S.A.	Kingdom of Spain
Combipress	CY/H/0154/002	319550302	Win Medica Pharmaceutical S.A.	Hellenic Republic
Aproxxamlo	ES/H/0594/001	94601/22-09-2020	Sanofi-Aventis Monoprosopi A.E.B.E	Hellenic Republic
Aproxxamlo	ES/H/0594/003	94603/22-09-2020	Sanofi-Aventis Monoprosopi A.E.B.E	Hellenic Republic
Combipress	CY/H/0154/001	023513	Win Medica Pharmaceutical S.A.	Republic of Cyprus
Combipress	CY/H/0154/003	023515	Win Medica Pharmaceutical S.A.	Republic of Cyprus
Combipress	CY/H/0154/003	319550401	Win Medica Pharmaceutical S.A.	Hellenic Republic
Combipress	CY/H/0154/002		Win Medica Pharmaceutical S.A.	Hellenic Republic
EBIMIA		57954/17-06-2021	Elpen Pharmaceutical Co. Inc.	Hellenic Republic

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
Aproxxamlo	ES/H/0594/004	85202	Sanofi Aventis S.A.	Kingdom of Spain
Combipress	CY/H/0154/004	023516	Win Medica Pharmaceutical S.A.	Republic of Cyprus
Aproxxamlo	ES/H/0594/002		Sanofi S.r.l.	Italian Republic
Aproxxamlo	ES/H/0594/002	94602/22-09-2020	Sanofi-Aventis Monoprosopi A.E.B.E	Hellenic Republic
Aproxxamlo	ES/H/0594/001	85199	Sanofi Aventis S.A.	Kingdom of Spain
Aproxxamlo	ES/H/0594/001		Sanofi S.r.l.	Italian Republic
Combipress	CY/H/0154/003		Win Medica Pharmaceutical S.A.	Hellenic Republic
Aproxxamlo	ES/H/0594/003	85201	Sanofi Aventis S.A.	Kingdom of Spain
Aproxxamlo	ES/H/0594/003		Sanofi S.r.l.	Italian Republic
EBIMIA		55599/17-06-2021	Elpen Pharmaceutical Co. Inc.	Hellenic Republic
Aproxxamlo	ES/H/0594/004		Sanofi S.r.l.	Italian Republic
Combipress	CY/H/0154/004		Win Medica Pharmaceutical S.A.	Hellenic Republic
Aproxxamlo	ES/H/0594/003	94603/22-09-2020	Sanofi-Aventis Monoprosopi A.E.B.E	Hellenic Republic
Aproxxamlo	ES/H/0594/004	94604/22-09-2020	Sanofi-Aventis Monoprosopi A.E.B.E	Hellenic Republic