



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

29 November 2018
EMA/880324/2018
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: enalapril

Procedure no.: PSUSA/00001211/201803



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
Enalapril 5mg Tablets	not available	PL 36722/0080	SPECIAL CONCEPT DEVELOPMENT (UK) LTD	UK
Enalapril 10mg Tablets	not available	PL 36722/0081	SPECIAL CONCEPT DEVELOPMENT (UK) LTD	UK
Enalapril 20mg Tablets	not available	PL 36722/0082	SPECIAL CONCEPT DEVELOPMENT (UK) LTD	UK
Enalapril Maleate 2.5mg Tablets	not available	PL 20416/0310	CRESCENT PHARMA LIMITED	UK
Enalapril Maleate 5mg Tablets	not available	PL 20416/0311	CRESCENT PHARMA LIMITED	UK
Enalapril Maleate 10mg Tablets	not available	PL 20416/0312	CRESCENT PHARMA LIMITED	UK
Enalapril Maleate 20mg Tablets	not available	PL 20416/0313	CRESCENT PHARMA LIMITED	UK
Hipoartel 20 mg comprimidos	not available	58.076	FAES FARMA, S.A.	ES
EnaHEXAL® i.v. 1,25 mg Injektionslösung	not available	26672.01.00	HEXAL AG	DE
Enalapril ratiopharm 10 mg comprimidos	not available	63.816	RATIOPHARM ESPAÑA S.A.	ES
Enalapril maleate 2.5mg tablets	not available	PL 21880/0068	MEDREICH PLC	UK
RENITEC 20 mg, comprimé	SE/H/0404/004	34009 327 090 6 9	MSD FRANCE	FR
RENITEC 5 mg, comprimé	SE/H/0404/002	34009 327 089 8 7	MSD FRANCE	FR
Renitec® 20 mg Tabletten	SE/H/0404/004	BE 129981	MSD BELGIUM BVBA/SPRL	BE
Renitec® 20 mg, tabletten	SE/H/0404/004	BE 129981	MSD BELGIUM BVBA/SPRL	BE
Renitec 5 mg tabletter	SE/H/0404/002	9145	MERCK SHARP & DOHME BV	FI
Renitec 20 mg tabletter	SE/H/0404/004	9146	MERCK SHARP & DOHME BV	FI
Renitec 10 mg tabletter	SE/H/0404/003	10207	MERCK SHARP & DOHME BV	FI
Renitec 5 mg Tabletten	SE/H/0404/002	1-18172	MERCK SHARP & DOHME GES.M.B.H.	AT
Renitec 10 mg tabletti	SE/H/0404/003	10207	MERCK SHARP & DOHME BV	FI

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Renitec 20 mg tabletter	SE/H/0404/004	10262	MERCK SHARP & DOHME BV	SE
RENITEC 10 mg, tabletten	SE/H/0404/003	RVG 10852	MERCK SHARP & DOHME BV	NL
Renitec, 20 mg, comprimidos	SE/H/0404/004	8589515	MERCK SHARP & DOHME, LDA.	PT
Innovace® 10 mg Tablets	SE/H/0404/003	PL 00025/0195	MERCK SHARP & DOHME LTD.	UK
INNOVACE 20 mg Tablets	SE/H/0404/004	PA 1286/11/04	MERCK SHARP & DOHME IRELAND (HUMAN HEALTH) LTD	IE
Innovace® 20 mg Tablets	SE/H/0404/004	PL 00025/0196	MERCK SHARP & DOHME LTD.	UK
Renitec 20 mg Tabletten	SE/H/0404/004	1-18174	MERCK SHARP & DOHME GES.M.B.H.	AT
Renitec 10 mg tabletter	SE/H/0404/003	10840	MERCK SHARP & DOHME BV	SE
RENITEC 20 mg comprimidos	SE/H/0404/004	57.773	MERCK SHARP & DOHME DE ESPAÑA, S.A	ES
Renitec 2,5 mg tabletter	SE/H/0404/001	11334	MERCK SHARP & DOHME BV	SE
INNOVACE 5 mg Tablets	SE/H/0404/002	PA 1286/11/02	MERCK SHARP & DOHME IRELAND (HUMAN HEALTH) LTD	IE
RENITEC 20 mg, tabletten	SE/H/0404/004	RVG 10576	MERCK SHARP & DOHME BV	NL
Innovace® 5 mg Tablets	SE/H/0404/002	PL 00025/0194	MERCK SHARP & DOHME LTD.	UK
Renitec 5 mg tabletter	SE/H/0404/002	10261	MERCK SHARP & DOHME BV	SE
Renitec, 5 mg, comprimidos	SE/H/0404/002	8589549	MERCK SHARP & DOHME, LDA.	PT
ENAPREN 5 mg compresse	SE/H/0404/002	025682042	MERCK SHARP & DOHME LTD.	IT
RENITEC 5 mg comprimidos	SE/H/0404/002	57.768	MERCK SHARP & DOHME DE ESPAÑA, S.A	ES
Renitec, 5 mg, comprimidos	SE/H/0404/002	8589523	MERCK SHARP & DOHME, LDA.	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
Innovace® 2.5 mg Tablets	SE/H/0404/001	PL 00025/0220	MERCK SHARP & DOHME LTD.	UK
Renitec 5 mg tabletti	SE/H/0404/002	9145	MERCK SHARP & DOHME BV	FI
INNOVACE 10 mg Tablets	SE/H/0404/003	PA 1286/11/03	MERCK SHARP & DOHME IRELAND (HUMAN HEALTH) LTD	IE
Enapren 20 mg compresse	SE/H/0404/004	025682079	MERCK SHARP & DOHME LTD.	IT
Renitec 10 mg Tabletten	SE/H/0404/003	1-18173	MERCK SHARP & DOHME GES.M.B.H.	AT
Enapren 20 mg compresse	SE/H/0404/004	025682028	MERCK SHARP & DOHME LTD.	IT
Renitec 20 mg tabletti	SE/H/0404/004	9146	MERCK SHARP & DOHME BV	FI
INNOVACE 2.5 mg Tablets	SE/H/0404/001	PA 1286/11/01	MERCK SHARP & DOHME IRELAND (HUMAN HEALTH) LTD	IE
Renitec, 20 mg, comprimidos	SE/H/0404/004	8589556	MERCK SHARP & DOHME, LDA.	PT
Renitec® 20 mg, comprimés	SE/H/0404/004	2010090876	MSD BELGIUM BVBA/SPRL	LU
Renitec® 20 mg, comprimés	SE/H/0404/004	BE 129981	MSD BELGIUM BVBA/SPRL	BE
XANEF 20 mg Tabletten Wirkstoff: Enalaprilmaleat	SE/H/0404/004	30056.03.00	MSD SHARP & DOHME GMBH	DE
XANEF 10 mg Tabletten Wirkstoff: Enalaprilmaleat	SE/H/0404/003	30056.02.00	MSD SHARP & DOHME GMBH	DE
XANEF 5 mg Tabletten Wirkstoff: Enalaprilmaleat	SE/H/0404/002	30056.01.00	MSD SHARP & DOHME GMBH	DE
XANEF Cor 2,5 mg Tabletten Wirkstoff: Enalaprilmaleat	SE/H/0404/001	30056.00.00	MSD SHARP & DOHME GMBH	DE
Renitec 5 mg, tabletten	SE/H/0404/002	RVG 10575	MERCK SHARP & DOHME BV	NL

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
RENITEC 20 mg, comprimé	SE/H/0404/004	34009 556 818 8 5	MSD FRANCE	FR
RENITEC 5 mg, comprimé	SE/H/0404/002	34009 556 817 1 7	MSD FRANCE	FR
RENITEC 20 mg, comprimé	SE/H/0404/004	34009 372 411 2 0	MSD FRANCE	FR
RENITEC 20 mg, comprimé	SE/H/0404/004	34009 381 832 7 6	MSD FRANCE	FR
Naprilene 20 mg compresse	SE/H/0404/003	025725072	ALFASIGMA S.P.A.	IT
Naprilene 20 mg compresse	SE/H/0404/003	025725021	ALFASIGMA S.P.A.	IT
Naprilene 5 mg compresse	SE/H/0404/002	025725045	ALFASIGMA S.P.A.	IT
Renitec 5, 5 mg, comprimidos	SE/H/0404/002	5743547	MERCK SHARP & DOHME, LDA.	PT
Renitec, 20 mg, comprimidos	SE/H/0404/004	5743554	MERCK SHARP & DOHME, LDA.	PT
Renitec 5 mg διακία	SE/H/0404/002	75284/31-10-2012	VIANEX S.A.	GR
Renitec 20 mg διακία	SE/H/0404/004	75283/31-10-2012	VIANEX S.A.	GR
CRINOREN 20 mg comprimidos	not available	57.965	VIFOR PHARMA ESPAÑA, S.L.	ES
CRINOREN 5 mg comprimidos	not available	57.964	VIFOR PHARMA ESPAÑA, S.L.	ES
Prilan 5 mg comprimidos	not available	2549590	CONFAR - CONSÓRCIO FARMACÊUTICO LDA	PT
Prilan 5 mg comprimidos	not available	2549491	CONFAR - CONSÓRCIO FARMACÊUTICO LDA	PT
Prilan 5 mg comprimidos	not available	2549590	CONFAR - CONSÓRCIO FARMACÊUTICO LDA	PT
Prilan 5 mg comprimidos	not available	2549491	CONFAR - CONSÓRCIO FARMACÊUTICO LDA	PT
Enalapril maleate 5 mg Tablets	not available	PL 44041/0012	NOUMED LIFE SCIENCES	UK

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Enalapril maleate 20 mg Tablets	not available	PL 44041/0014	NOUMED LIFE SCIENCES	UK
Enalapril maleate 10 mg Tablets	not available	PL 44041/0013	NOUMED LIFE SCIENCES	UK
RENITEC 10 mg comprimate	not available	7498/2015/01	MERCK SHARP & DOHME ROMANIA SRL	RO
RENITEC 20 mg comprimate	not available	7499/2015/01	MERCK SHARP & DOHME ROMANIA SRL	RO
RENITEC 5 mg comprimate	not available	7500/2015/01	MERCK SHARP & DOHME ROMANIA SRL	RO
Renitec, 5 mg tabletid	not available	089394	MERCK SHARP & DOHME OU	EE
Renitec 5 mg tabletter	not available	7018	MERCK SHARP & DOHME BV	NO
Renitec 2,5 mg tabletta	not available	OGYI-T-4198/01	MSD PHARMA HUNGARY KFT.	HU
РЕНИТЕК 20 mg таблетки	not available	20010652	MERCK SHARP & DOHME BULGARIA EOOD	BG
РЕНИТЕК 10 mg таблетки	not available	20010650	MERCK SHARP & DOHME BULGARIA EOOD	BG
РЕНИТЕК 5 mg таблетки	not available	20010651	MERCK SHARP & DOHME BULGARIA EOOD	BG
Renitec 10 mg tabletta	not available	OGYI-T-4198/03	MSD PHARMA HUNGARY KFT.	HU
Renitec 20 mg tabletta	not available	OGYI-T-4198/04	MSD PHARMA HUNGARY KFT.	HU
Renitec 5 mg tabletta	not available	OGYI-T-4198/02	MSD PHARMA HUNGARY KFT.	HU
Renitec Forte, 20 mg tabletid	not available	089594	MERCK SHARP & DOHME OU	EE
Renitec 10 mg tabletter	not available	7626	MERCK SHARP & DOHME BV	NO
Renitec 20 mg tabletter	not available	7019	MERCK SHARP & DOHME BV	NO
CONVERTEN 5 mg compresse	not available	025681038	DAIICHI SANKYO EUROPE GMBH	IT
CONVERTEN 20 mg compresse	not available	025681026	DAIICHI SANKYO EUROPE GMBH	IT

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CONVERTEN 20 mg compresse	not available	025681065	DAIICHI SANKYO EUROPE GMBH	IT
enalapril cinfa 10 mg comprimidos	not available	73.300	LABORATORIOS CINFA, S.A.	ES
Enalapril Terapia 5 mg comprimate	not available	6337/2014/01	TERAPIA S.A.	RO
Enalapril Terapia 10 mg comprimate	not available	6338/2014/01	TERAPIA S.A.	RO
Enalapril Terapia 20 mg comprimate	not available	6339/2014/01	TERAPIA S.A.	RO
Enalapril Sandoz® 30 mg Tabletten	NL/H/0925/001	67838.00.00	HEXAL AG	DE
NAPRILENE 5 mg comprimidos	not available	57.873	ALFASIGMA ESPAÑA, S.L.	ES
NAPRILENE 20 mg comprimidos	not available	57.872	ALFASIGMA ESPAÑA, S.L.	ES
Naprilene 20 mg compresse	SE/H/0404/003	025725072	ALFASIGMA S.P.A.	IT
Naprilene 20 mg compresse	SE/H/0404/003	025725021	ALFASIGMA S.P.A.	IT
Naprilene 5 mg compresse	SE/H/0404/002	025725045	ALFASIGMA S.P.A.	IT
ENALAPRIL RANBAXY 2,5 mg, comprimé	FR/H/0501/001	NL 41417	RANBAXY PHARMACIE GENERIQUES	FR
ENALAPRIL RANBAXY 10 mg, comprimé	FR/H/0501/003	NL 41419	RANBAXY PHARMACIE GENERIQUES	FR
Prilan 5 mg comprimidos	not available	2549590	CONFAR - CONSÓRCIO FARMACÊUTICO LDA	PT
Prilan 5 mg comprimidos	not available	2549491	CONFAR - CONSÓRCIO FARMACÊUTICO LDA	PT