



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

30 November 2023
EMA/551509/2023
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: enalapril

Procedure no.: PSUSA/00001211/202303



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
CONVERTEN 5 mg compresse	not available	025681038	TEOFARMA S.R.L.	IT
CONVERTEN 20 mg compresse	not available	025681026	TEOFARMA S.R.L.	IT
CONVERTEN 20 mg compresse	not available	025681065	TEOFARMA S.R.L.	IT
Renitec 2,5 mg tabletta	not available	OGYI-T-4198/01	ORGANON HUNGARY KFT.	HU
Renitec 10 mg tabletta	not available	OGYI-T-4198/03	ORGANON HUNGARY KFT.	HU
Renitec 5 mg tabletta	not available	OGYI-T-4198/02	ORGANON HUNGARY KFT.	HU
Renitec 20 mg tabletta	not available	OGYI-T-4198/04	ORGANON HUNGARY KFT.	HU
Enalapril maleate 20 mg Tablets.	not available	PL 44041/0014	NOUMED LIFE SCIENCES	XI
Enalaprilmaleaat Aurobindo 2,5 mg, tabletten	PT/H/1920/001	RVG 122189	AUROBINDO PHARMA B.V.	NL
Enalapril Aurovitas 10 mg comprimidos	PT/H/1920/003	83.712	AUROVITAS SPAIN,S.A.U.	ES
EnaHEXAL® i.v. 1,25 mg Injektionslösung	not available	26672.01.00	HEXAL AG	DE
Naprilene 20 mg compresse	not available	025725072	ALFASIGMA S.P.A.	IT
Naprilene 20 mg compresse	not available	025725021	ALFASIGMA S.P.A.	IT
Naprilene 5 mg compresse	not available	025725045	ALFASIGMA S.P.A.	IT
Enalapril Davur 2,5 mg comprimidos.	not available	63570	TEVA PHARMA S.L.U.,	ES
Enalapril Davur 10 mg comprimidos.	not available	63569	TEVA PHARMA S.L.U.,	ES
Enalapril Belmac 10 mg comprimidos.	not available	63567	TEVA PHARMA S.L.U.,	ES
Enalapril Belmac 2,5 mg comprimidos.	not available	63568	TEVA PHARMA S.L.U.,	ES
РЕНИТЕК 20 mg таблетки	not available	20010652	N.V. ORGANON	BG
РЕНИТЕК 10 mg таблетки	not available	20010650	N.V. ORGANON	BG
enalapril cinfa 10 mg comprimidos	not available	73.300	LABORATORIOS CINFA, S.A.	ES
Enalapril Terapia 5 mg comprimate	not available	12129/2019/01	TERAPIA S.A.	RO
Enalapril Terapia 10 mg comprimate	not available	12130/2019/01	TERAPIA S.A.	RO

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Enalapril Terapia 20 mg comprimate	not available	12131/2019/01	TERAPIA S.A.	RO
Hipoartel 20 mg comprimidos	not available	58.076	FAES FARMA, S.A.	ES
Enalapril 5mg Tablets.	not available	PL 36282/0007	RIA GENERICS LTD	XI
Enalapril 10mg Tablets.	not available	PL 36282/0008	RIA GENERICS LTD	XI
Enalapril 20mg Tablets.	not available	PL 36282/0009	RIA GENERICS LTD	XI
Enalapril maleate 5 mg Tablets	not available	PL 44041/0012	NOUMED LIFE SCIENCES	XI
Renitec 20 mg tabletter	not available	7019	N.V. ORGANON	NO
Renitec 10 mg tabletter	not available	7626	N.V. ORGANON	NO
RENITEC 5 mg comprimate	not available	7498/2015/01	ORGANON BIOSCIENCES S.R.L.	RO
RENITEC 10 mg comprimate	not available	7499/2015/01	ORGANON BIOSCIENCES S.R.L.	RO
RENITEC 20 mg comprimate	not available	7500/2015/01	ORGANON BIOSCIENCES S.R.L.	RO
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
Renitec® 5 mg δισκία	SE/H/0404/002	75284/31-10-2012	VIANEX S.A.	GR
Renitec® 20 mg δισκία	SE/H/0404/004	75283/31-10-2012	VIANEX S.A.	GR
XANEF 5 mg Tabletten Wirkstoff: Enalaprilmaleat	SE/H/0404/002	30056.01.00	ORGANONHEALTHCARE GMBH	DE
XANEF 10 mg Tabletten Wirkstoff: Enalaprilmaleat	SE/H/0404/003	30056.02.00	ORGANONHEALTHCARE GMBH	DE
XANEF 20 mg Tabletten Wirkstoff: Enalaprilmaleat	SE/H/0404/004	30056.03.00	ORGANONHEALTHCARE GMBH	DE
Renitec 20 mg, comprimés	SE/H/0404/004	2010090876	ORGANONBELGIUM	LU
Renitec 20 mg Tabletten	SE/H/0404/004	BE129981	ORGANONBELGIUM	BE
Renitec 20 mg, comprimés	SE/H/0404/004	BE129981	ORGANONBELGIUM	BE
Renitec 20 mg, tabletten	SE/H/0404/004	BE129981	ORGANONBELGIUM	BE
Renitec 5 mg Tabletten	SE/H/0404/002	1-18172	ORGANONHEALTHCARE GMBH	AT
Renitec 10 mg Tabletten	SE/H/0404/003	1-18173	ORGANONHEALTHCARE GMBH	AT

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Renitec 20 mg Tabletten	SE/H/0404/004	1-18174	ORGANONHEALTHCARE GMBH	AT
RENITEC 5 mg, comprimé	SE/H/0404/002	34009 327 089 8 7	ORGANON FRANCE	FR
RENITEC 20 mg, comprimé	SE/H/0404/004	34009 327 090 6 9	ORGANON FRANCE	FR
RENITEC 20 mg, comprimé	SE/H/0404/004	34009 372 411 2 0	ORGANON FRANCE	FR
RENITEC 20 mg, comprimé	SE/H/0404/004	34009 381 832 7 6	ORGANON FRANCE	FR
RENITEC 5 mg, comprimé	SE/H/0404/002	34009 556 817 1 7	ORGANON FRANCE	FR
RENITEC 20 mg, comprimé	SE/H/0404/004	34009 556 818 8 5	ORGANON FRANCE	FR
RENITEC 5 mg comprimidos	SE/H/0404/002	57768	ORGANONSALUD, S.L.	ES
RENITEC 20 mg comprimidos	SE/H/0404/004	57773	ORGANONSALUD, S.L.	ES
Renitec 20 mg Comprimidos	SE/H/0404/004	5743554	ORGANONPORTUGAL, SOCIEDADE UNIPESSOAL LDA.	PT
Renitec 20 mg Comprimidos	SE/H/0404/004	8589515	ORGANONPORTUGAL, SOCIEDADE UNIPESSOAL LDA.	PT
Renitec 20 mg Comprimidos	SE/H/0404/004	8589556	ORGANONPORTUGAL, SOCIEDADE UNIPESSOAL LDA.	PT
INNOVACE 2.5 mg Tablets	SE/H/0404/	PA23198/005/001	ORGANON PHARMA (IRELAND) LIMITED	IE
INNOVACE 5 mg Tablets	SE/H/0404/002	PA23198/005/002	ORGANON PHARMA (IRELAND) LIMITED	IE
INNOVACE 10 mg Tablets	SE/H/0404/003	PA23198/005/003	ORGANON PHARMA (IRELAND) LIMITED	IE
INNOVACE 20 mg Tablets	SE/H/0404/004	PA23198/005/004	ORGANON PHARMA (IRELAND) LIMITED	IE
Renitec 5 mg, tabletten	SE/H/0404/002	RVG 10575	N.V. ORGANON	NL
Renitec 20 mg, tabletten	SE/H/0404/004	RVG 10576	N.V. ORGANON	NL
RENITEC 10 mg, tabletten	SE/H/0404/003	RVG 10852	N.V. ORGANON	NL
Renitec 5 mg tabletter	SE/H/0404/002	10261	N.V. ORGANON	SE
Renitec 20 mg tabletter	SE/H/0404/004	10262	N.V. ORGANON	SE
Renitec 10 mg tabletter	SE/H/0404/003	10840	N.V. ORGANON	SE
Renitec 2,5 mg tabletter	SE/H/0404/	11334	N.V. ORGANON	SE

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Renitec 10 mg tablett	SE/H/0404/003	10207	N.V. ORGANON	FI
Renitec 10 mg tabletti	SE/H/0404/003	10207	N.V. ORGANON	FI
Renitec 5 mg tablett	SE/H/0404/002	9145	N.V. ORGANON	FI
Renitec 5 mg tabletti	SE/H/0404/002	9145	N.V. ORGANON	FI
Renitec 20 mg tablett	SE/H/0404/004	9146	N.V. ORGANON	FI
Renitec 20 mg tabletti	SE/H/0404/004	9146	N.V. ORGANON	FI
Enapren 20 mg compresse	SE/H/0404/004	025682028	ORGANON ITALIA S.R.L.	IT
Enapren 5 mg compresse	SE/H/0404/002	025682042	ORGANON ITALIA S.R.L.	IT
Enapren 20 mg compresse	SE/H/0404/004	025682079	ORGANON ITALIA S.R.L.	IT
Enapren 5 mg compresse	SE/H/0404/002	025682319	ORGANON ITALIA S.R.L.	IT
Enalapril maleate 20 mg Tablets.	not available	PL 44041/0014	NOUMED LIFE SCIENCES	XI
Innovace® 5 mg Tablets	not available	PL 00025/0194	ORGANON PHARMA (UK) LIMITED	XI
Innovace® 10 mg Tablets	not available	PL 00025/0195	ORGANON PHARMA (UK) LIMITED	XI
Innovace® 20 mg Tablets	not available	PL 00025/0196	ORGANON PHARMA (UK) LIMITED	XI
Innovace® 2.5 mg Tablets	not available	PL 00025/0220	ORGANON PHARMA (UK) LIMITED	XI
Enalapril maleate 10 mg Tablets.	not available	PL 44041/0013	NOUMED LIFE SCIENCES	XI
Enalapril ratiopharm 10 mg comprimidos	not available	63816	TEVA PHARMA S.L.U.,	ES
Enalapril Maleate 2.5mg Tablets	not available	PL 20416/0310	CRESCENT PHARMA LIMITED	XI
Enalapril Maleate 5mg Tablets	not available	PL 20416/0311	CRESCENT PHARMA LIMITED	XI
Enalapril Maleate 10mg Tablets	not available	PL 20416/0312	CRESCENT PHARMA LIMITED	XI
Enalapril Maleate 20mg Tablets	not available	PL 20416/0313	CRESCENT PHARMA LIMITED	XI