



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

6 May 2021
EMA/154395/2022
Pharmacovigilance Risk Assessment Committee (PRAC)

List of nationally authorised medicinal products

Active substance(s): lisinopril, lisinopril / hydrochlorothiazide

Procedure No.: PSUSA/00010532/202009



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
LISIPRIL 5 mg tablety	not available	58/382/03-C	HEXAL AG	CZ
LISIPRIL 20 mg tablety	not available	58/384/03-C	HEXAL AG	CZ
LISIPRIL 10 mg tablety	not available	58/383/03-C	HEXAL AG	CZ
Lisinopril 10 mg Tablets	AT/H/0895/002	PL 04416/1036	SANDOZ LTD	XI
Zestril 10 mg, tablets.	not available	12875	ASTRAZENECA AB	CY
Zestril 20mg, tablets.	not available	12876	ASTRAZENECA AB	CY
Zestril 5mg, tablets.	not available	12874	ASTRAZENECA AB	CY
Lisinopril + HCT 10 mg/12.5 mg tablets	not available	PL 20416/0597	CRESCENT PHARMA LIMITED	UK
Lisinopril + HCT 20 mg/12.5 mg tablets	not available	PL 20416/0598	CRESCENT PHARMA LIMITED	UK
PRINZIDE δισκία 20/12.5mg	not available	29495/10-05-2012	VIANEX S.A.	GR
PRINZIDE δισκία 20/25mg	not available	41922/07/06-06-2008	VIANEX S.A.	GR
ALAPRIL 5 mg compresse	not available	026837043	NEOPHARMED GENTILI SPA	IT
ALAPRIL 20 mg compresse	not available	026837029	NEOPHARMED GENTILI SPA	IT
ALAPRIL 5 mg compresse	not available	026837017	NEOPHARMED GENTILI SPA	IT
ALAPRIL 20 mg compresse	not available	026837056	NEOPHARMED GENTILI SPA	IT
ZESTORETIC 20 mg/12,5 mg, comprimé sécable	not available	NL 15492	ASTRAZENECA S.A.S.	FR
Prinzide 20 mg + 12,5 mg compresse.	not available	027481011	NEOPHARMED GENTILI SPA	IT
Lisinopril Sandoz 5 mg tabletten	AT/H/0895/001	BE244964	SANDOZ N.V.	BE
Lisinopril 5 mg Tablets	AT/H/0895/001	PL 04416/1035	SANDOZ LTD	UK (NI)
PRINIVIL 20 mg compresse.	not available	026830024	NEOPHARMED GENTILI SPA	IT
PRINIVIL 5 mg compresse	not available	026830012	NEOPHARMED GENTILI SPA	IT
Lisinopril Aurobindo 40 mg, tabletten	NL/H/1976/004	RVG 32686	AUROBINDO PHARMA B.V.	NL
PRINIVIL 20 mg compresse.	not available	026830024	NEOPHARMED GENTILI SPA	IT
PRINIVIL 5 mg compresse	not available	026830012	NEOPHARMED GENTILI SPA	IT
Zestoretic 20 mg/12,5 mg comprimés	not available	2004098411	ASTRAZENECA S.A. / N.V.	LU
PRINIVIL 5 mg comprimidos	not available	59.128	ROVI PHARMA INDUSTRIAL SERVICES S.A.U.	ES
PRINIVIL 20 mg comprimidos	not available	59.129	ROVI PHARMA INDUSTRIAL SERVICES S.A.U.	ES
Lisinopril Sandoz 20 mg tabletten	AT/H/0895/003	BE244982	SANDOZ N.V.	BE

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
Lisinopril 20 mg Tablets	AT/H/0895/003	PL 04416/1037	SANDOZ LTD	UK (NI)
Lisinopril Teva 30 mg, tabletten	not available	RVG 33797	TEVA NEDERLAND B.V.	NL
Zestoretic 20 mg + 12,5 mg compresse.	not available	A.I.C. 027482025	ASTRAZENECA S.P.A.	IT
Zestoretic 20 mg + 12,5 mg compresse.	not available	A.I.C. 027482037	ASTRAZENECA S.P.A.	IT
Zestoretic 20 mg + 12,5 mg compresse.	not available	A.I.C. 027482013	ASTRAZENECA S.P.A.	IT
Zestril 10 mg tabletter	SE/H/0527/003	10871	ASTRAZENECA AB	SE
Zestril 30 mg tabletter	SE/H/0527/005	15268	ASTRAZENECA AB	SE
Zestril 2,5 mg tabletter	SE/H/0527/001	11646	ASTRAZENECA AB	SE
Zestril Mite, 10 mg, comprimidos	SE/H/0527/003	8708248	ASTRAZENECA PRODUTOS FARMACEUTICOS LDA	PT
Zestril Mite, 10 mg, comprimidos	SE/H/0527/003	8708255	ASTRAZENECA PRODUTOS FARMACEUTICOS LDA	PT
ZESTRIL 10 mg compresse	SE/H/0527/003	26834034	ASTRAZENECA S.P.A.	IT
Zestril-5, 5 mg, comprimidos	SE/H/0527/002	8708214	ASTRAZENECA PRODUTOS FARMACEUTICOS LDA	PT
Zestril 5 mg tabletter	SE/H/0527/002	10870	ASTRAZENECA AB	SE
Zestril-5, 5 mg, comprimidos	SE/H/0527/002	8708206	ASTRAZENECA PRODUTOS FARMACEUTICOS LDA	PT
ZESTRIL 5 mg compresse	SE/H/0527/002	026834010	ASTRAZENECA S.P.A.	IT
ZESTRIL 5 mg compresse	SE/H/0527/002	026834061	ASTRAZENECA S.P.A.	IT
ZESTRIL 5 mg compresse	SE/H/0527/002	026834059	ASTRAZENECA S.P.A.	IT
ZESTRIL 10mg, δισκία	SE/H/0527/003	3788/05	ASTRAZENECA S.A	GR
Zestril-10, 10 mg, tabletten.	SE/H/0527/003	BE396645	ASTRAZENECA S.A. / N.V.	BE
Zestril-10, 10 mg, comprimés.	SE/H/0527/003	BE396645	ASTRAZENECA S.A. / N.V.	BE
Zestril-10, 10 mg, comprimés.	SE/H/0527/003	BE237413	ASTRAZENECA S.A. / N.V.	BE
Zestril 10 mg tablets	SE/H/0527/003	PA 1019/026/002	ASTRAZENECA AB	IE
ZESTRIL 5mg, δισκία	SE/H/0527/002	3788/05	ASTRAZENECA S.A	GR
Zestril-5, 5 mg, tabletten.	SE/H/0527/002	BE396611	ASTRAZENECA S.A. / N.V.	BE
Zestril-5, 5 mg, comprimés.	SE/H/0527/002	BE396611	ASTRAZENECA S.A. / N.V.	BE
Zestril-10, 10 mg, comprimés.	SE/H/0527/003	BE396645	ASTRAZENECA S.A. / N.V.	BE
Zestril-10, 10 mg, tabletten.	SE/H/0527/003	BE237413	ASTRAZENECA S.A. / N.V.	BE
Zestril-20, 20 mg, tabletten.	SE/H/0527/004	BE396681	ASTRAZENECA S.A. / N.V.	BE
Zestril-20, 20 mg, comprimés.	SE/H/0527/004	BE141671	ASTRAZENECA S.A. / N.V.	BE

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Zestril-20, 20 mg, comprimés.	SE/H/0527/004	BE396681	ASTRAZENECA S.A. / N.V.	BE
Zestril-20, 20 mg, tabletten.	SE/H/0527/004	BE141671	ASTRAZENECA S.A. / N.V.	BE
Zestril-20, 20 mg, comprimés.	SE/H/0527/004	BE396672	ASTRAZENECA S.A. / N.V.	BE
Zestril-20, 20 mg, tabletten.	SE/H/0527/004	BE396672	ASTRAZENECA S.A. / N.V.	BE
Zestril-10, 10 mg, tabletten.	SE/H/0527/003	BE396645	ASTRAZENECA S.A. / N.V.	BE
Zestril, 5 mg, tablets	SE/H/0527/002	PA 1019/026/001	ASTRAZENECA AB	IE
Zestril-5, 5 mg, comprimés	SE/H/0527/002	0173/11091286	ASTRAZENECA S.A. / N.V.	LU
Zestril 5 mg tablets	SE/H/0527/002	17901/0061	ASTRAZENECA UK LIMITED	UK
Acemin 20 mg - Tabletten	SE/H/0527/004	1-19015	ASTRAZENECA OSTERREICH GMBH	AT
Acemin 10 mg - Tabletten	SE/H/0527/003	1-19013	ASTRAZENECA OSTERREICH GMBH	AT
Acemin 30 mg - Tabletten	SE/H/0527/005	1-23335	ASTRAZENECA OSTERREICH GMBH	AT
Acemin 2,5 mg - Tabletten	SE/H/0527/001	1-21290	ASTRAZENECA OSTERREICH GMBH	AT
Acemin 5 mg - Tabletten	SE/H/0527/002	1-19014	ASTRAZENECA OSTERREICH GMBH	AT
Zestril 20 mg comprimidos	SE/H/0527/004	59.127	ASTRAZENECA FARMACÉUTICA SPAIN, S.A.	ES
Zestril 10 mg tablets	SE/H/0527/003	17901/0062	ASTRAZENECA UK LIMITED	UK
Zestril-20, 20 mg, comprimés.	SE/H/0527/004	0173/11091287	ASTRAZENECA S.A. / N.V.	LU
ZESTRIL 20mg, δισκία	SE/H/0527/004	3788/05	ASTRAZENECA S.A	GR
Zestril 20 mg tabletter	SE/H/0527/004	10872	ASTRAZENECA AB	SE
Zestril-5, 5 mg, comprimés.	SE/H/0527/002	BE141556	ASTRAZENECA S.A. / N.V.	BE
Zestril-5, 5 mg, tabletten.	SE/H/0527/002	BE141556	ASTRAZENECA S.A. / N.V.	BE
ZESTRIL 20 mg compresse	SE/H/0527/004	026834022	ASTRAZENECA S.P.A.	IT
Zestril, 20 mg, comprimidos	SE/H/0527/004	8708230	ASTRAZENECA PRODUTOS FARMACEUTICOS LDA	PT
ZESTRIL 20 mg compresse	SE/H/0527/004	026834085	ASTRAZENECA S.P.A.	IT
Zestril, 20 mg, comprimidos	SE/H/0527/004	8708222	ASTRAZENECA PRODUTOS FARMACEUTICOS LDA	PT
ZESTRIL 20 mg compresse	SE/H/0527/004	026834073	ASTRAZENECA S.P.A.	IT
Zestril-5, 5 mg, comprimidos	SE/H/0527/002	4545380	ASTRAZENECA PRODUTOS FARMACEUTICOS LDA	PT
Zestril, 20 mg, tablets	SE/H/0527/004	PA 1019/026/003	ASTRAZENECA AB	IE
Zestril 20 mg tablets	SE/H/0527/004	17901/0063	ASTRAZENECA UK LIMITED	UK
ZESTRIL 20 mg, comprimé	SE/H/0527/004	34009 398 904 6 3	ASTRAZENECA S.A.S.	FR
ZESTRIL 20 mg, comprimé	SE/H/0527/004	34009 559181 0 3	ASTRAZENECA S.A.S.	FR
ZESTRIL 20 mg, comprimé	SE/H/0527/004	34009 329 990 4 0	ASTRAZENECA S.A.S.	FR

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
ZESTRIL 5 mg, comprimé sécable	SE/H/0527/002	34009 398 902 3 4	ASTRAZENECA S.A.S.	FR
ZESTRIL 5 mg, comprimé sécable	SE/H/0527/002	34009 559 182 7 1	ASTRAZENECA S.A.S.	FR
ZESTRIL 5 mg, comprimé sécable	SE/H/0527/002	34009 329 991 0 1	ASTRAZENECA S.A.S.	FR
Zestril 10 mg, tabletter	SE/H/0527/003	7636	ASTRAZENECA AS	NO
Zestril 5 mg, tabletter	SE/H/0527/002	7635	ASTRAZENECA AS	NO
Zestril 2,5 mg, tabletter	SE/H/0527/001	7812	ASTRAZENECA AS	NO
Zestril 20 mg, tabletter	SE/H/0527/004	7637	ASTRAZENECA AS	NO
Zestril-5, 5 mg, tabletten.	SE/H/0527/002	BE396636	ASTRAZENECA S.A. / N.V.	BE
Zestril-5, 5 mg, comprimés.	SE/H/0527/002	BE396636	ASTRAZENECA S.A. / N.V.	BE
Zestril-10, 10 mg, comprimés.	SE/H/0527/003	BE396663	ASTRAZENECA S.A. / N.V.	BE
Zestril-10, 10 mg, tabletten.	SE/H/0527/003	BE396663	ASTRAZENECA S.A. / N.V.	BE
Zestril-20, 20 mg, tabletten.	SE/H/0527/004	BE396697	ASTRAZENECA S.A. / N.V.	BE
Zestril-20, 20 mg, comprimés.	SE/H/0527/004	BE396697	ASTRAZENECA S.A. / N.V.	BE
Acercomp®, 20 mg/12,5 mg Tabletten	not available	22242.00.00	ASTRAZENECA GMBH	DE
Lisinopril Apotex 2,5 mg, tabletten	not available	RVG 27120	APOTEX EUROPE B.V.	NL
Lisinopril 2.5 mg Tablets	not available	PL 36722/0087	SPECIAL CONCEPT DEVELOPMENT (UK) LTD	UK
Lisinopril 5 mg Tablets	not available	PL 36722/0088	SPECIAL CONCEPT DEVELOPMENT (UK) LTD	UK
Lisinopril 10 mg Tablets	not available	PL 36722/0089	SPECIAL CONCEPT DEVELOPMENT (UK) LTD	UK
Lisinopril 20 mg Tablets	not available	PL 36722/0090	SPECIAL CONCEPT DEVELOPMENT (UK) LTD	UK
Lisinopril 2.5mg Tablets	not available	PL 25298/0118	BROWN & BURK UK LIMITED	UK (NI)
Lisinopril 2.5mg Tablets	not available	PL 25298/0118	BROWN & BURK UK LIMITED	UK (NI)
Lisinopril 5mg Tablets	not available	PL 25298/0119	BROWN & BURK UK LIMITED	UK (NI)
Lisinopril 5mg Tablets	not available	PL 25298/0119	BROWN & BURK UK LIMITED	UK (NI)
Lisinopril 10mg Tablets	not available	PL 25298/0120	BROWN & BURK UK LIMITED	UK (NI)
Lisinopril 10mg Tablets	not available	PL 25298/0120	BROWN & BURK UK LIMITED	UK (NI)
Lisinopril 20mg Tablets	not available	PL 25298/0121	BROWN & BURK UK LIMITED	UK (NI)
Lisinopril 20mg Tablets	not available	PL 25298/0121	BROWN & BURK UK LIMITED	UK (NI)
Lisinopril 5mg Tablets	MT/H/0501/001	PL 20416/0352	CRESCENT PHARMA LIMITED	UK
Lisinopril 10mg Tablets	MT/H/0501/002	PL 20416/0353	CRESCENT PHARMA LIMITED	UK
Lisinopril Crescent 5 mg Tablets	MT/H/0501/001	MA1317/01501	CRESCENT PHARMA INTERNATIONAL LIMITED	MT

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
Lisinopril Crescent 10 mg Tablets	MT/H/0501/002	MA1317/01502	CRESCENT PHARMA INTERNATIONAL LIMITED	MT
PRINIVIL, 5 mg, tabletki	not available	4864	MSD POLSKA SP. Z O.O.	PL
PRINIVIL, 10 mg, tabletki	not available	4865	MSD POLSKA SP. Z O.O.	PL
PRINIVIL, 20 mg, tabletki	not available	4866	MSD POLSKA SP. Z O.O.	PL
Lisinopril 2.5mg Tablets	not available	PL 20416/0351	CRESCENT PHARMA LIMITED	UK
Lisinopril 20mg Tablets	not available	PL 20416/0354	CRESCENT PHARMA LIMITED	UK
Zestoretic 20 mg/12,5 mg comprimés	not available	BE152591	ASTRAZENECA S.A. / N.V.	BE
Zestoretic 20 mg/12,5 mg tabletten	not available	BE152591	ASTRAZENECA S.A. / N.V.	BE
PRINIVIL	not available	43094/18-06-2013	VIANEX S.A.	GR
PRINIVIL	not available	48371/18-06-2013	VIANEX S.A.	GR
PRINIVIL	not available	48369/18-06-2013	VIANEX S.A.	GR
PRINIVIL	not available	48370/18-06-2013	VIANEX S.A.	GR
Zestril, 10 mg, tablets.	not available	MA 046/02702	ASTRAZENECA AB	MT
Zestril, 20 mg, tablets.	not available	MA 046/02703	ASTRAZENECA AB	MT
Zestril, 5 mg, tablets.	not available	MA 046/02701	ASTRAZENECA AB	MT
PRINIVIL® PLUS 20/12,5 mg comprimidos	not available	59.583	ROVI PHARMA INDUSTRIAL SERVICES S.A.U.	ES
Acecomb mite - Tabletten	not available	1-19511	ASTRAZENECA OSTERREICH GMBH	AT
Acecomb semi - Tabletten	not available	1-21095	ASTRAZENECA OSTERREICH GMBH	AT
Acecomb - Tabletten	not available	1-19510	ASTRAZENECA OSTERREICH GMBH	AT
ALAPRIL 5 mg compresse	not available	026837043	NEOPHARMED GENTILI SPA	IT
ALAPRIL 20 mg compresse	not available	026837029	NEOPHARMED GENTILI SPA	IT
ALAPRIL 5 mg compresse	not available	026837017	NEOPHARMED GENTILI SPA	IT
ALAPRIL 20 mg compresse	not available	026837056	NEOPHARMED GENTILI SPA	IT
Lisinopril 5mg Tablets	MT/H/0501/001	PL 20416/0352	CRESCENT PHARMA LIMITED	UK
Lisinopril 10mg Tablets	MT/H/0501/002	PL 20416/0353	CRESCENT PHARMA LIMITED	UK
Lisinopril Crescent 5 mg Tablets	MT/H/0501/001	MA1317/01501	CRESCENT PHARMA INTERNATIONAL LIMITED	MT
Lisinopril Crescent 10 mg Tablets	MT/H/0501/002	MA1317/01502	CRESCENT PHARMA INTERNATIONAL LIMITED	MT
Lisinopril 2.5 mg Tablets	UK/H/0551/001	PL 04416/1034	SANDOZ LTD	UK (NI)
Zestoretic 20 mg/12,5 mg comprimidos.	not available	59.582	ASTRAZENECA FARMACÉUTICA SPAIN, S.A.	ES
Zestoretic	not available	13839	ASTRAZENECA AB	CY

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Zestoretic 20 mg/12.5 mg Tablets	not available	PA 1019/025/002	ASTRAZENECA AB	IE
Zestoretic 10 mg/12.5 mg Tablets	not available	PA 1019/025/001	ASTRAZENECA AB	IE
ZESTORETIC	not available	37776/07/16-07-2008	ASTRAZENECA S.A	GR
Nalapres 20 mg + 12,5 mg compresse.	not available	027553015	NEOPHARMED GENTILI SPA	IT
Lisinopril 5mg Tablets	not available	PL 11311/0395	TILLOMED LABORATORIES LTD	UK
Lisinopril 2.5mg Tablets	not available	PL 11311/0394	TILLOMED LABORATORIES LTD	UK
Lisinopril 20mg Tablets	not available	PL 11311/0397	TILLOMED LABORATORIES LTD	UK
Lisinopril 10mg Tablets	not available	PL 11311/0396	TILLOMED LABORATORIES LTD	UK