



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

29 September 2022
EMA/794351/2022
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: loratadine

Procedure no.: PSUSA/00001907/202202



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
Clarityn 10 mg – Tabletten	BE/H/0128/001	1-19490	BAYER AUSTRIA GMBH	AT
Claritine 1 mg/ml siroop	BE/H/0128/002	BE159835	BAYER SA NV	BE
Claritine 1 mg/ml sirop	BE/H/0128/002	BE159835	BAYER SA NV	BE
Claritine 1 mg/ml Sirup	BE/H/0128/002	BE159835	BAYER SA NV	BE
Claritine 10 mg comprimés	BE/H/0128/001	BE139124	BAYER SA NV	BE
Claritine 10 mg comprimés	BE/H/0128/001	BE467191	BAYER SA NV	BE
Claritine 10 mg tabletten	BE/H/0128/001	BE139124	BAYER SA NV	BE
Claritine 10 mg Tabletten	BE/H/0128/001	BE139124	BAYER SA NV	BE
Claritine 10 mg Tabletten	BE/H/0128/001	BE467191	BAYER SA NV	BE

Claritine 10 mg tabletten	BE/H/0128/001	BE467191	BAYER SA NV	BE
Loratadine SP 10 mg comprimés	BE/H/0130/001	BE249575	BAYER SA NV	BE
Loratadine SP 10 mg comprimés	BE/H/0130/001	BE467226	BAYER SA NV	BE
Loratadine SP 10 mg Tabletten	BE/H/0130/001	BE249575	BAYER SA NV	BE
Loratadine SP 10 mg Tabletten	BE/H/0130/001	BE467226	BAYER SA NV	BE
Loratadine SP 10mg tabletten	BE/H/0130/001	BE249575	BAYER SA NV	BE
Loratadine SP 10mg tabletten	BE/H/0130/001	BE467226	BAYER SA NV	BE
Кларитин 1 mg/ml сироп	not available	20000222	BAYER BULGARIA EOOD	BG
Кларитин 10 mg таблетки	not available	20000221	BAYER BULGARIA EOOD	BG

CLARITYNE 10 mg δισκία	not available	12546	BAYER HELLAS SA	CY
Claritine 10 mg tablety	not available	24/001/92-S/C	BAYER SRO	CZ
Clarityn, tabletter	BE/H/0128/001	12582	BAYER AB	DK
Claritine, 10 mg tabletid	not available	160497	BAYER UAB	EE
Clarityne 10 mg comprimidos	BE/H/0128/001	58.518	BAYER HISPANIA SL	ES
CLARITYNE 10mg, comprimé	BE/H/0128/001	34009 329 891 6 4	BAYER HEALTHCARE	FR
CLARITYNE 10mg, comprimé	BE/H/0128/001	34009 329 892 2 5	BAYER HEALTHCARE	FR
CLARITYNE 10mg, comprimé	BE/H/0128/001	34009 274 882 0 7	BAYER HEALTHCARE	FR
CLARITYNE 10mg, comprimé	BE/H/0128/001	34009 331 391 7 9	BAYER HEALTHCARE	FR

CLARITYNE 10mg, comprimé	BE/H/0128/001	34009 365 673 5 1	BAYER HEALTHCARE	FR
CLARITYNE 10 mg δισκία	BE/H/0128/001	65448/2-10-2015	BAYER HELLAS SA	GR
Claritine 10 mg tablete	not available	HR-H-487098981-01	BAYER DOO	HR
Claritine Alergija 1 mg/ml sirup	not available	HR-H-890875636	BAYER DOO	HR
Claritine Alergija 10 mg tablete	not available	HR-H-264690912-01	BAYER DOO	HR
Claritine 10 mg tabletta	not available	OGYI-T-1650/01	BAYER HUNGARIA KFT	HU
Claritine 10 mg tabletta	not available	OGYI-T-1650/03	BAYER HUNGARIA KFT	HU
Claritine 10 mg tabletta	not available	OGYI-T-1650/07	BAYER HUNGARIA KFT	HU
Claritine 10 mg tabletta	not available	OGYI-T-1650/08	BAYER HUNGARIA KFT	HU

Clarityn 10 mg tablets	BE/H/0128/001	PA1410/075/001	BAYER LTD	IE
Clarityn 1mg/1ml Syrup	BE/H/0128/002	PA1410/075/002	BAYER LTD	IE
Clarityn 10 mg töflur	BE/H/0128/001	870042	BAYER AB	IS
Clarityn 10 mg compresse	BE/H/0128/001	027075086	BAYER SPA	IT
Clarityn 10 mg compresse	BE/H/0128/001	027075100	BAYER SPA	IT
Clarityn 10 mg compresse	BE/H/0128/001	027075011	BAYER SPA	IT
Fristamin 10 mg compresse	BE/H/0130/001	027076013	FABBRICA ITALIANA RITROVATI MEDICINALI ED AFFINI F.I.R.M.A. - S.P.A.	IT
Fristamin 10 mg compresse	BE/H/0130/001	027076076	FABBRICA ITALIANA RITROVATI MEDICINALI ED AFFINI F.I.R.M.A. - S.P.A.	IT
Fristamin 10 mg compresse	BE/H/0130/001	027076064	FABBRICA ITALIANA RITROVATI MEDICINALI ED AFFINI F.I.R.M.A. - S.P.A.	IT

Claritine 10 mg tabletès	not available	LT/1/97/1686/001	BAYER UAB	LT
Claritine 10 mg tabletès	not available	LT/1/97/1686/002	BAYER UAB	LT
Claritine 10 mg tabletès	not available	98-0216	BAYER UAB	LV
Claritine, stroop 1 mg/ml	BE/H/0128/002	RVG 13492	BAYER BV	NL
Claritine, tabletten 10 mg	BE/H/0128/001	RVG 13388	BAYER BV	NL
Clarityn 10 mg tabletter	BE/H/0128/001	00/7429	BAYER AB	NO
Claritine, 1 mg/ml, syrop	not available	R/3554	BAYER SP.Z.O.O	PL
CLARITINE, 10 mg, tabletki	not available	R/1215	BAYER SP.Z.O.O	PL
Claritine 1 mg/ml xarope	BE/H/0128/002	9777912	BAYER PORTUGAL LDA	PT

Claritine 10 mg comprimidos	BE/H/0128/001	9702407	BAYER PORTUGAL LDA	PT
Claritine 1 mg/ml sirop	not available	11020/2018/01	BAYER SRL	RO
Claritine 1 mg/ml sirop	not available	11020/2018/02	BAYER SRL	RO
Claritine 1 mg/ml sirop	not available	11020/2018/03	BAYER SRL	RO
Claritine 10 mg comprimate	not available	11021/2018/01	BAYER SRL	RO
Proactin 10 mg comprimate	not available	11022/2018/01	BAYER SRL	RO
Clarityn 1 mg/ml sirap	BE/H/0128/002	11471	BAYER AB	SE
Clarityn 10 mg tabletter	BE/H/0128/001	10895	BAYER AB	SE
Claritine 10 mg tablete	not available	H/94/00397/001	BAYER D.O.O	SI

Claritine 5 mg/5 ml sirup	not available	H/94/00397/002	BAYER D.O.O	SI
Claritine S 10 mg tablete	not available	H/94/00397/003	BAYER D.O.O	SI
Claritine 10 mg tablety	not available	24/0001/92-S	BAYER SPOL SRO	SK
Asda one-a-day hayfever and allergy 10mg tablets	not available	PL 16028/0080	GALPHARM HEALTHCARE LIMITED	XI
Asda one-a-day hayfever and allergy 10mg tablets	not available	PL 16028/0081	GALPHARM HEALTHCARE LIMITED	XI
Asda one-a-day hayfever and allergy 10mg tablets	not available	PL 16028/0081	GALPHARM HEALTHCARE LIMITED	XI
Boots one-a-day hayfever and allergy relief 10 mg tablets	not available	PL 16028/0080	GALPHARM HEALTHCARE LIMITED	XI
Boots one-a-day hayfever and allergy relief 10 mg tablets	not available	PL 16028/0081	GALPHARM HEALTHCARE LIMITED	XI
Boots one-a-day hayfever and allergy relief 10 mg tablets	not available	PL 16028/0081	GALPHARM HEALTHCARE LIMITED	XI

Galpharm one-a-day allergy and hayfever relief 10mg tablets	not available	PL 16028/0080	GALPHARM HEALTHCARE LIMITED	XI
Galpharm one-a-day allergy and hayfever relief 10mg tablets	not available	PL 16028/0081	GALPHARM HEALTHCARE LIMITED	XI
Galpharm one-a-day allergy and hayfever relief 10mg tablets	not available	PL 16028/0081	GALPHARM HEALTHCARE LIMITED	XI
Health Essentials one-a-day hayfever and allergy relief 10mg tablets	not available	PL 16028/0080	GALPHARM HEALTHCARE LIMITED	XI
Lorapaed Allergy Relief 5 mg/5 ml Oral Solution	not available	PL 04917/0141	PINEWOOD LABORATORIES LIMITED	XI
Loratadine 10 mg tablets	not available	PL 36687/0230	TORRENT PHARMA (UK) LTD.	XI
Loratadine 5mg/5ml Oral Solution	not available	PL 36687/0231	TORRENT PHARMA (UK) LTD.	XI
Morrisons One-a-Day Hayfever & Allergy Relief 10mg Tablets	not available	PL 16028/0080	GALPHARM HEALTHCARE LIMITED	XI
Morrisons One-a-Day Hayfever & Allergy Relief 10mg Tablets	not available	PL 16028/0081	GALPHARM HEALTHCARE LIMITED	XI

Morrisons One-a-Day Hayfever & Allergy Relief 10mg Tablets	not available	PL 16028/0081	GALPHARM HEALTHCARE LIMITED	XI
Numark one-a-day allergy 10mg tablets	not available	PL 16028/0080	GALPHARM HEALTHCARE LIMITED	XI
Numark one-a-day allergy 10mg tablets	not available	PL 16028/0081	GALPHARM HEALTHCARE LIMITED	XI
Numark one-a-day allergy 10mg tablets	not available	PL 16028/0081	GALPHARM HEALTHCARE LIMITED	XI
Optipharma one-a-day Hayfever and Allergy relief 10mg tablets	not available	PL 16028/0080	GALPHARM HEALTHCARE LIMITED	XI
Sainsbury's Healthcare one-a-day allergy and hayfever relief 10mg tablets	not available	PL 16028/0080	GALPHARM HEALTHCARE LIMITED	XI
Sainsbury's one-a-day allergy and hayfever relief 10mg tablets	not available	PL 16028/0080	GALPHARM HEALTHCARE LIMITED	XI
Sainsbury's one-a-day allergy and hayfever relief 10mg tablets	not available	PL 16028/0081	GALPHARM HEALTHCARE LIMITED	XI
Sainsbury's one-a-day allergy and hayfever relief 10mg tablets	not available	PL 16028/0081	GALPHARM HEALTHCARE LIMITED	XI

Superdrug one-a-day hayfever and allergy 10mg tablets	not available	PL 16028/0080	GALPHARM HEALTHCARE LIMITED	XI
Tesco one-a-day hayfever and allergy relief 10mg tablets	not available	PL 16028/0080	GALPHARM HEALTHCARE LIMITED	XI
Tesco one-a-day hayfever and allergy relief 10mg tablets	not available	PL 16028/0081	GALPHARM HEALTHCARE LIMITED	XI
Tesco one-a-day hayfever and allergy relief 10mg tablets	not available	PL 16028/0081	GALPHARM HEALTHCARE LIMITED	XI
Ultarin 10 mg Tablets	not available	PL 36687/0374	TORRENT PHARMA (UK) LTD.	XI
Value Health one-a-day allergy relief 10 mg tablets	not available	PL 16028/0080	GALPHARM HEALTHCARE LIMITED	XI