



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

29 September 2017
EMA/658556/2017
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: loratadine

Procedure no.: PSUSA/00001907/201702



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
Lorapaed Allergy Relief 5 mg/5 ml Oral Solution	not available	04917/0141	PINEWOOD LABORATORIES LIMITED	UK
Loratadine EG 10 mg Tabletten	NL/H/0297/001	BE272002	EUROGENERICS N.V./S.A.	BE
Loratadine EG 10 mg comprimés.	NL/H/0297/001	BE272002	EUROGENERICS N.V./S.A.	BE
Loratadine EG 10 mg tabletten	NL/H/0297/001	BE272002	EUROGENERICS N.V./S.A.	BE
Claritine Reditabs 10 mg lyophilisats oraux	BE/H/0128/004	2008049757	BAYER SA NV	LU
Claritine Reditabs 10 mg lyophilisaat voor oraal gebruik	BE/H/0128/004	BE225513	BAYER SA NV	BE
Clarityn Rapide Allergy 10mg Tablets	BE/H/0128/004	PL 00010/0655	BAYER PLC	UK
Clarityn 10 mg – Tabletten	BE/H/0128/001(OTC)	1-19490	BAYER AUSTRIA GMBH	AT
Claritine 10 mg comprimés	BE/H/0128/001	2008049755	BAYER SA NV	LU
Loratadine SP 10 mg comprimés	BE/H/0130/001	2008049756	BAYER SA NV	LU
Clarityn Allergy 10mg Tablets	BE/H/0128/001	PL 00010/0657	BAYER PLC	UK
Clarityn Allergy 10mg Tablets	BE/H/0176/001	PL 00010/0662	BAYER PLC	UK
Claritine 10 mg tabletten	BE/H/0128/001	BE139124	BAYER SA NV	BE
Alertrin Anti-Allergie 10 mg tabletten	BE/H/0176/001	BE401177	BAYER SA NV	BE
Loratadine SP 10mg tabletten	BE/H/0130/001	BE249575	BAYER SA NV	BE
Claritine 1 mg/ml sirop	BE/H/0128/002(OTC)	2008049758	BAYER SA NV	LU
Clarityn Allergy 1mg/ml Syrup	BE/H/0128/002	PL 00010/0656	BAYER PLC	UK
CLARITINE 1 mg/ml siroop	BE/H/0128/002	BE159835	BAYER SA NV	BE
Claritine 10 mg tabletès	not available	LT/1/97/1686/001	BAYER UAB	LT
Claritine, 10 mg tabletid	not available	160497	BAYER UAB	EE
Claritine 1 mg/ml sirupas	not available	LT/1/97/1686/003	BAYER UAB	LT

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
Claritine 10 mg tabletés	not available	LT/1/97/1686/002	BAYER UAB	LT
Clarityn Rapide Allergy 10 mg Tablets	BE/H/0128/004	PA 1410/075/003	BAYER LTD	IE
Clarityn 1 mg/1ml Syrup	BE/H/0128/002	PA1410/075/002	BAYER LTD	IE
Clarityn 10 mg Tablets	BE/H/0128/001	PA1410/075/001	BAYER LTD	IE
Clarityn 10 mg tabletit	BE/H/0128/001	11737	BAYER OY	FI
CLARITYNE 10mg, comprimé	BE/H/0128/001	34009 329 891 6 4	BAYER HEALTHCARE	FR
CLARITYNE 1mg/ml, sirop	BE/H/0128/002	34009 335 605 1 5	BAYER HEALTHCARE	FR
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 szirup	not available	OGYI-T-1650/06	BAYER HUNGARIA KFT	HU
Claritine 10 mg tabletta	not available	OGYI-T-1650/01	BAYER HUNGARIA KFT	HU
Clarityn, syrup	BE/H/0128/002(OTC)	13896	BAYER AB	DK
Clarityn, tabletter	BE/H/0128/001(OTC)	12582	BAYER AB	DK
Claritine 10 mg tabletta	not available	OGYI-T-1650/03	BAYER HUNGARIA KFT	HU
Clarityn 1 mg/ml saft	BE/H/0128/002(OTC)	940184	BAYER AB	IS
Clarityn 10 mg töflur	BE/H/0128/001(OTC)	870042	BAYER AB	IS
Claritine 1 mg/ml xarope	BE/H/0128/002	9777912	BAYER PORTUGAL LDA	PT
Clarityn 10 mg tabletter	BE/H/0128/001(OTC)	00/7429	BAYER AB	NO
Clarityn 1 mg/ml sirap	BE/H/0128/002(OTC)	11471	BAYER AB	SE
Clarityn 10 mg tabletter	BE/H/0128/001(OTC)	10895	BAYER AB	SE
Claritine 1 mg/ml sirups	not available	98-0215	BAYER UAB	LV
Claritine 10 mg tabletes	not available	98-0217	BAYER UAB	LV

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
Claritine 10 mg tabletes	not available	98-0216	BAYER UAB	LV
Claritine 10 mg comprimidos	BE/H/0128/001	9702407	BAYER PORTUGAL LDA	PT
Claritine Zydis 10 mg liofilizado oral	BE/H/0128/004(RX)	3969680	BAYER PORTUGAL LDA	PT
Claritine Zydis 10 mg liofilizado oral	BE/H/0128/004(RX)	3812088	BAYER PORTUGAL LDA	PT
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 Allergy 10mg Tablets	not available	MA513/05401	BAYER PLC	MT
Clarityn Allergy 1mg/1ml Syrup	not available	MA513/05402	BAYER PLC	MT
CLARITYNE 10 mg δισκία	not available	12546	BAYER HELLAS SA	CY
CLARITYNE 1 mg/ml σιρόπι	not available	19908	BAYER HELLAS SA	CY
Claritine 10 mg tabletten	BE/H/0128/001(OTC)	BE467191	BAYER SA NV	BE
Lisino S, 10 mg Tabletten Wirkstoff: Loratadin	BE/H/0128/001	38143.00.00	BAYER VITAL GMBH	DE
Claritine 1mg/ml sirup	not available	24/1061/92-S	BAYER SPOL SRO	SK
Claritine 10 mg tablety	not available	24/0001/92-S	BAYER SPOL SRO	SK
Claritine 1mg/ml sirup	not available	24/1061/92-S/C	BAYER SRO	CZ
Claritine 10 mg tablety	not available	24/001/92-S/C	BAYER SRO	CZ
Clarityn 10 mg liofilizzato orale	BE/H/0128/004	027075062	BAYER SPA	IT
Clarityn 1 mg/ml sciroppo	BE/H/0128/002	027075023	BAYER SPA	IT
Кларитин 1 mg/ml сироп	not available	20000222	BAYER BULGARIA EOOD	BG
Кларитин 10 mg таблетки	not available	20000221	BAYER BULGARIA EOOD	BG
Claritine 1 mg/ml sirop	not available	6216/2006/01	BAYER SRL	RO

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
Clarityne 1 mg/ml jarabe	BE/H/0128/002	59.141	BAYER HISPANIA SL	ES
Claritine 10 mg comprimate	not available	6360/2006/01	BAYER SRL	RO
Claritine 10 mg comprimate	not available	6217/2006/01	BAYER SRL	RO
Clarityn 10 mg compresse	BE/H/0128/001	027075098	BAYER SPA	IT
Clarityn 10 mg compresse	BE/H/0128/001	027075086	BAYER SPA	IT
Clarityn 10 mg compresse	BE/H/0128/001	027075100	BAYER SPA	IT
Clarityne 10 mg comprimidos	BE/H/0128/001(OTC)	58.518	BAYER HISPANIA SL	ES
Claritine 5 mg/5 ml sirup	not available	H/94/00397/002	BAYER D.O.O	SI
Claritine 10 mg tablete	not available	H/94/00397/001	BAYER D.O.O	SI
Claritine S 10 mg tablete	not available	H/94/00397/003	BAYER D.O.O	SI
CLARITYNE 1mg/ml, sirop	BE/H/0128/002	34009 335 604 5 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
Loratadine SP 10mg tabletten	BE/H/0130/001	BE467226	BAYER SA NV	BE
Alertrin Anti-Allergie 10 mg tabletten	BE/H/0176/001	BE467182	BAYER SA NV	BE
Clarityn 10 mg compresse	BE/H/0128/001	027075011	BAYER SPA	IT
Claritine 10 mg tableta	not available	OGYI-T-1650/07	BAYER HUNGARIA KFT	HU
Claritine 1 mg/ml sirop	not available	6216/2006/02	BAYER SRL	RO
Claritine 1 mg/ml sirup	not available	HR-H-890875636	BAYER DOO	HR

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
Claritine 10 mg tablete	not available	HR-H-487098981	BAYER DOO	HR
Claritine Alergija 10 mg tablete	not available	HR-H-264690912	BAYER DOO	HR
CLARITYNE 10 mg επιγλώσσια δισκία	BE/H/0128/004	65450/2-10-2015	BAYER HELLAS SA	GR
CLARITYNE 1 mg/ml σιρόπι	BE/H/0128/002	65449/2-10-2015	BAYER HELLAS SA	GR
CLARITYNE 10 mg δισκία	BE/H/0128/001	65448/2-10-2015	BAYER HELLAS SA	GR
Claritine 10 mg tabletta	not available	OGYI-T-1650/08	BAYER HUNGARIA KFT	HU
Bell's Healthcare Hayfever & Allergy 10mg tablets	not available	PL 20395/0088	RELON CHEM LIMITED	UK
Peach Hayfever & Allergy 10mg tablets	not available	PL 20395/0088	RELON CHEM LIMITED	UK
Haylief Hayfever & Allergy 10mg Tablets	not available	PL 20395/0088	RELON CHEM LIMITED	UK
Tesco One a day Hayfever & Allergy 10mg Tablets	not available	PL 20395/0088	RELON CHEM LIMITED	UK
Essential Waitrose Hayfever & Allergy 10mg tablets	not available	PL 20395/0088	RELON CHEM LIMITED	UK
HealthEssentials Hayfever & Allergy 10mg Tablets	not available	PL 20395/0088	RELON CHEM LIMITED	UK
Relonchem Hayfever & Allergy 10mg tablets	not available	PL 20395/0088	RELON CHEM LIMITED	UK
Claritine Reditabs 10 mg lyophilisats oraux	BE/H/0128/004	2008049757	BAYER SA NV	LU
Claritine Reditabs 10 mg lyophilisaat voor oraal gebruik	BE/H/0128/004	BE225513	BAYER SA NV	BE
Clarityn Rapide Allergy 10mg Tablets	BE/H/0128/004	PL 00010/0655	BAYER PLC	UK
Clarityn 10 mg – Tabletten	BE/H/0128/001(OTC)	1-19490	BAYER AUSTRIA GMBH	AT
Claritine 10 mg comprimés	BE/H/0128/001	2008049755	BAYER SA NV	LU

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
Loratadine SP 10 mg comprimés	BE/H/0130/001	2008049756	BAYER SA NV	LU
Clarityn Allergy 10mg Tablets	BE/H/0128/001	PL 00010/0657	BAYER PLC	UK
Clarityn Allergy 10mg Tablets	BE/H/0176/001	PL 00010/0662	BAYER PLC	UK
Claritine 10 mg tabletten	BE/H/0128/001	BE139124	BAYER SA NV	BE
Alertrin Anti-Allergie 10 mg tabletten	BE/H/0176/001	BE401177	BAYER SA NV	BE
Loratadine SP 10mg tabletten	BE/H/0130/001	BE249575	BAYER SA NV	BE
Claritine 1 mg/ml sirop	BE/H/0128/002(OTC)	2008049758	BAYER SA NV	LU
Clarityn Allergy 1mg/ml Syrup	BE/H/0128/002	PL 00010/0656	BAYER PLC	UK
CLARITINE 1 mg/ml siroop	BE/H/0128/002	BE159835	BAYER SA NV	BE
Claritine 10 mg tabletės	not available	LT/1/97/1686/001	BAYER UAB	LT
Claritine, 10 mg tabletid	not available	160497	BAYER UAB	EE
Claritine 1 mg/ml sirupas	not available	LT/1/97/1686/003	BAYER UAB	LT
Claritine 10 mg tabletės	not available	LT/1/97/1686/002	BAYER UAB	LT
Clarityn Rapide Allergy 10 mg Tablets	BE/H/0128/004	PA 1410/075/003	BAYER LTD	IE
Clarityn 1 mg/1ml Syrup	BE/H/0128/002	PA1410/075/002	BAYER LTD	IE
Clarityn 10 mg Tablets	BE/H/0128/001	PA1410/075/001	BAYER LTD	IE
Clarityn 10 mg tabletit	BE/H/0128/001	11737	BAYER OY	FI
CLARITYNE 10mg, comprimé	BE/H/0128/001	34009 329 891 6 4	BAYER HEALTHCARE	FR
CLARITYNE 1mg/ml, sirop	BE/H/0128/002	34009 335 605 1 5	BAYER HEALTHCARE	FR
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 szirup	not available	OGYI-T-1650/06	BAYER HUNGARIA KFT	HU
Claritine 10 mg tabletta	not available	OGYI-T-1650/01	BAYER	HU

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
			HUNGARIA KFT	
Clarityn, syrup	BE/H/0128/002(OTC)	13896	BAYER AB	DK
Clarityn, tabletter	BE/H/0128/001(OTC)	12582	BAYER AB	DK
Claritine 10 mg tabletta	not available	OGYI-T-1650/03	BAYER HUNGARIA KFT	HU
Clarityn 1 mg/ml saft	BE/H/0128/002(OTC)	940184	BAYER AB	IS
Clarityn 10 mg töflur	BE/H/0128/001(OTC)	870042	BAYER AB	IS
Claritine 1 mg/ml xarope	BE/H/0128/002	9777912	BAYER PORTUGAL LDA	PT
Clarityn 10 mg tabletter	BE/H/0128/001(OTC)	00/7429	BAYER AB	NO
Clarityn 1 mg/ml sirap	BE/H/0128/002(OTC)	11471	BAYER AB	SE
Clarityn 10 mg tabletter	BE/H/0128/001(OTC)	10895	BAYER AB	SE
Claritine 1 mg/ml sirups	not available	98-0215	BAYER UAB	LV
Claritine 10 mg tabletes	not available	98-0217	BAYER UAB	LV
Claritine 10 mg tabletes	not available	98-0216	BAYER UAB	LV
Claritine 10 mg comprimidos	BE/H/0128/001	9702407	BAYER PORTUGAL LDA	PT
Claritine Zydis 10 mg liofilizado oral	BE/H/0128/004(RX)	3969680	BAYER PORTUGAL LDA	PT
Claritine Zydis 10 mg liofilizado oral	BE/H/0128/004(RX)	3812088	BAYER PORTUGAL LDA	PT
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 Allergy 10mg Tablets	not available	MA513/05401	BAYER PLC	MT
Clarityn Allergy 1mg/1ml Syrup	not available	MA513/05402	BAYER PLC	MT
CLARITYNE 10 mg δισκία	not available	12546	BAYER HELLAS SA	CY
CLARITYNE 1 mg/ml σιρόπι	not available	19908	BAYER HELLAS SA	CY

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
Claritine 10 mg tabletten	BE/H/0128/001(OTC)	BE467191	BAYER SA NV	BE
Lisino S, 10 mg Tabletten Wirkstoff: Loratadin	BE/H/0128/001	38143.00.00	BAYER VITAL GMBH	DE
Claritine 1mg/ml sirup	not available	24/1061/92-S	BAYER SPOL SRO	SK
Claritine 10 mg tablety	not available	24/0001/92-S	BAYER SPOL SRO	SK
Claritine 1mg/ml sirup	not available	24/1061/92-S/C	BAYER SRO	CZ
Claritine 10 mg tablety	not available	24/001/92-S/C	BAYER SRO	CZ
Clarityn 10 mg liofilizzato orale	BE/H/0128/004	027075062	BAYER SPA	IT
Clarityn 1 mg/ml sciroppo	BE/H/0128/002	027075023	BAYER SPA	IT
Кларитин 1 mg/ml сироп	not available	20000222	BAYER BULGARIA EOOD	BG
Кларитин 10 mg таблетки	not available	20000221	BAYER BULGARIA EOOD	BG
Claritine 1 mg/ml sirop	not available	6216/2006/01	BAYER SRL	RO
Clarityne 1 mg/ml jarabe	BE/H/0128/002	59.141	BAYER HISPANIA SL	ES
Claritine 10 mg comprimate	not available	6360/2006/01	BAYER SRL	RO
Claritine 10 mg comprimate	not available	6217/2006/01	BAYER SRL	RO
Clarityn 10 mg compresse	BE/H/0128/001	027075098	BAYER SPA	IT
Clarityn 10 mg compresse	BE/H/0128/001	027075086	BAYER SPA	IT
Clarityn 10 mg compresse	BE/H/0128/001	027075100	BAYER SPA	IT
Clarityne 10 mg comprimidos	BE/H/0128/001(OTC)	58.518	BAYER HISPANIA SL	ES
Claritine 5 mg/5 ml sirup	not available	H/94/00397/002	BAYER D.O.O	SI
Claritine 10 mg tablete	not available	H/94/00397/001	BAYER D.O.O	SI
Claritine S 10 mg tablete	not available	H/94/00397/003	BAYER D.O.O	SI
CLARITYNE 1mg/ml, sirop	BE/H/0128/002	34009 335 604 5 4	BAYER HEALTHCARE	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
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
Loratadine SP 10mg tabletten	BE/H/0130/001	BE467226	BAYER SA NV	BE
Alertrin Anti-Allergie 10 mg tabletten	BE/H/0176/001	BE467182	BAYER SA NV	BE
Clarityn 10 mg compresse	BE/H/0128/001	027075011	BAYER SPA	IT
Claritine 10 mg tabletta	not available	OGYI-T-1650/07	BAYER HUNGARIA KFT	HU
Claritine 1 mg/ml sirop	not available	6216/2006/02	BAYER SRL	RO
Claritine 1 mg/ml sirup	not available	HR-H-890875636	BAYER DOO	HR
Claritine 10 mg tablete	not available	HR-H-487098981	BAYER DOO	HR
Claritine Alergija 10 mg tablete	not available	HR-H-264690912	BAYER DOO	HR
CLARITYNE 10 mg επιγλώσσια δισκία	BE/H/0128/004	65450/2-10-2015	BAYER HELLAS SA	GR
CLARITYNE 1 mg/ml σιρόπι	BE/H/0128/002	65449/2-10-2015	BAYER HELLAS SA	GR
CLARITYNE 10 mg δισκία	BE/H/0128/001	65448/2-10-2015	BAYER HELLAS SA	GR
Claritine 10 mg tabletta	not available	OGYI-T-1650/08	BAYER HUNGARIA KFT	HU
Brown & Burk Once-A-Day Hayfever & Allergy 10mg Tablets	not available	PL 25298/0117	BROWN & BURK UK LIMITED	UK
Brown & Burk Once-A-Day Hayfever & Allergy 10mg Tablets	not available	PL 25298/0117	BROWN & BURK UK LIMITED	UK
Brown & Burk Once-A-Day Hayfever & Allergy 10mg Tablets	not available	PL 25298/0117	BROWN & BURK UK LIMITED	UK

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
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	027076052	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
Loratadine 10 mg Tablets	not available	PL 25298/0019	BROWN & BURK UK LIMITED	UK
Loratadine 10 mg Tablets	not available	PL 25298/0034	BROWN & BURK UK LIMITED	UK