ANNEX I

LIST OF THE INVENTED NAMES, PHARMACEUTICAL FORMS, STRENGTHS OF THE MEDICINAL PRODUCTS, ROUTE OF ADMINISTRATION, APPLICANTS/MARKETING AUTHORISATION HOLDERS, PACKAGING AND PACKAGE SIZES IN THE MEMBER STATES

PLEASE NOTE THAT APPLICANTS ARE NOT INCLUDED IN THIS ANNEX FOR CONFIDENTIALITY REASONS

Member State	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical Form	Route of administration	Packaging	Package size
AU	Aesca chem.pharm. Fabrik GmbH., Badner Straße 23, A-2514 Traiskirchen, Austria	Clarityn 10 mg - lösliche Tabletten	10 mg	Soluble tablet	Oral use	Tablet container	10, 30
AU	Aesca chem.pharm. Fabrik GmbH., Badner Straße 23, A-2514 Traiskirchen, Austria	Clarityn 10 mg - Lyotabletten	10 mg	Oral lyophilisate	Oral use	Blister	10, 30
AU	Aesca chem.pharm. Fabrik GmbH., Badner Straße 23, A-2514 Traiskirchen, Austria	Clarityn 10 mg Tabletten	10 mg	Tablet	Oral use	Blister	10, 30
AU	Aesca chem.pharm. Fabrik GmbH., Badner Straße 23, A-2514 Traiskirchen, Austria	Clarityn 5mg/5ml – Sirup	5 mg/5 ml	Syrup	Oral use	Bottle (glass)	60 ml
AU	Aesca chem.pharm. Fabrik GmbH., Badner Straße 23, A-2514 Traiskirchen, Austria	Loratadin Aesca 10mg - Tabletten	10 mg	Tablet	Oral use	Blister	10, 30
AU	Aesca chem.pharm. Fabrik GmbH., Badner Straße 23, A-2514 Traiskirchen, Austria	Loratadin Aesca 5mg/5ml - Sirup	5 mg/5 ml	Syrup	Oral use	Bottle (glass)	60 ml
AU	Aesca chem.pharm. Fabrik GmbH., Badner Straße 23, A-2514 Traiskirchen, Austria	Loratyn 10 mg - Brausetabletten	10 mg	Effervescent tablet	Oral use	Tablet container	10

Member State	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical Form	Route of administration	Packaging	Package size
AU	Aesca chem.pharm. Fabrik GmbH., Badner Straße 23, A-2514 Traiskirchen, Austria	Loratyn 10 mg - Lyotabletten	10 mg	Oral lyophilisate	Oral use	Blister	10, 30
AU	Arcana Arzneimittel GmbH., Zimbagasse 5, A-1147 Wien Austria	Loratadin arcana 10 mg-Filmtabletten	10 mg	Film-coated tablet	Oral use	Blister	5, 7, 10, 14, 15, 20, 21, 30, 50, 100
AU	Lannacher Heilmittelwerke GmbH, Schloßplatz 1, A-8502 Lannach Austria	Lorat 10 mg - Tabletten	10 mg	Tablet	Oral use	Blister	7, 10, 20, 30, 50, 100
AU	Liconsa S.A. Gran Via Carlos III, 98 ES-08028 Barcelona Spain	Chemotadin 10 mg - Tabletten	10 mg	Tablet	Oral use	Blister	7, 10, 20, 30, 50, 100
AU	Lindopharm GmbH., Neustraße 82, D-40721 Hilden Germany	Loratadin Lindopharm 10 mg Tabletten	10 mg	Tablet	Oral use	Blister	7, 10, 20, 30, 50, 100
AU	Ratiopharm Arzneimittel Vertriebs-GmbH, Alöbert Schweitzer Gasse 3, A-1147 Wien Austria	Loratadin ratiopharm 10 mg - Tabletten	10 mg	Tablet	Oral use	Blister	7, 20, 50, 100
AU	Sandoz GmbH., A-6250 Kundl/Tirol Austria	Lictyn 10 mg - Tabletten	10 mg	Tablet	Oral use	Blister	7, 10, 14, 20, 21, 30, 50, 60, 100, 250

Member State	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical Form	Route of administration	Packaging	Package size
AU	Stada Arzneimittel GmbH, Heiligenstädterstraße 52/8, A-1190 Wien, Austria	Loratadine "Stada" 10 mg Tabletten	10 mg	Tablet	Oral use	Blister	1, 5, 7, 10, 14, 15, 20, 21, 30, 50, 60, 90, 100, 250
AU	Stada Arzneimittel GmbH, Heiligenstädterstraße 52/8, A-1190 Wien, Austria	Loratadine "Stada" 1 mg/ml Sirup	5mg/5 ml	Syrup	Oral use	Bottle (glass)	50, 60, 100, 120, 150ml
BE	Omega Pharma N.V. Venecoweg 26 B-9810 Nazareth Belgium	Sanelor	10 mg	Tablet	Oral use	Blister	10
BE	Laboratoires Irex Avenue galilee F-92350 Le Plessis-Robinson, Cedex France	Loratadine irex	10 mg	Tablet	Oral use	Blister (PVC/Alu)	7, 20, 30, 50, 100
BE	Merck NV Brusselsesteenweg 288 B-3090 Overijse Belgium	Merck-loratadine	10 mg	Film-coated tablet	Oral use	Blister (PVC/Alu)	5, 7, 10, 14, 15, 20, 21, 30, 50, 100

Member State	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical Form	Route of administration	Packaging	Package size
BE	Schering Plough N.V. Rue de Stalle 73 B-1180 Brussels Belgium	Claritine	10 mg	Tablet	Oral use	Blister	7, 21 1, 2, 5, 7, 10, 14, 20, 21, 28, 30, 42, 50, 56, 100, 500 - for export
BE	Schering Plough N.V. Rue de Stalle 73 B-1180 Brussels Belgium	Claritine	10 mg	Effervescent tablet	Oral use	Blister	10, 21 10, 14, 15, 21, 30 - for export
BE	Schering Plough N.V. Rue de Stalle 73 B-1180 Brussels Belgium	Claritine	1 mg/ml	Syrup	Oral use	Bottle	100 ml 50, 60, 100, 120, 150 ml – for export
BE	Schering Plough N.V. Rue de Stalle 73 B-1180 Brussels Belgium	Claritine Reditabs	10 mg	Oral Lyophilisate	Oral use	Blister	10, 20, 30
DK	1A Farma Herstedøstervej 27-29 DK-2620 Albertslund. Denmark	Loratadin 1A Pharma	10 mg	Tablet	Oral use	Blister	10, 30, 100
DK	A/S GEA Farmaceutiske Fabrik, Holger Danskes Vej 89, DK-2000 Frederiksberg, Denmark	Geklimon	10 mg	Tablet	Oral use	Blister	10, 30, 100
DK	Ct-Arzneimittel GmbH	Loratadin ct	10 mg	Tablet	Oral use	Blister	Not

Member State	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical Form	Route of administration	Packaging	Package size
	Lengeder Str. 42a D-13407 Berlin Germany						marketed at the moment
DK	Durascan Medicinal Products A/S Svendborgvej 243, DK-5260 Odense S, Denmark	Oratyn	10 mg	Tablet	Oral use	Blister	5, 10, 30, 100
DK	HEXAL AG Industriestr. 25 D-83607 Holzkirchen Germany	Medallerg	10 mg	Tablet	Oral use	Blister	Not marketed at the moment
DK	Lichtenstein Pharmazeutica GmbH Industriestrasse 10 D-56218 Mulheim-Karlich Germany	Loratadin Lichtenstein	10 mg	Tablet	Oral use	Blister	Not marketed at the moment
DK	Linconsa SA. Gran Via Carlos III 98, 7 Planta ES-08028 Barcelona Spain	Chemolorat	10 mg	Tablet	Oral use	Blister	Not marketed at the moment
DK	Linconsa SA. Gran Via Carlos III 98, 7 Planta ES-08028 Barcelona Spain	Chemotadin	10 mg	Tablet	Oral use	Blister	Not marketed at the moment
DK	Linconsa SA. Gran Via Carlos III 98, 7 Planta ES-08028 Barcelona Spain	Licatidin	10 mg	Tablet	Oral use	Blister	Not marketed at the moment
DK	Linconsa SA. Gran Via Carlos III 98, 7 Planta ES-08028 Barcelona Spain	Loralic	10 mg	Tablet	Oral use	Blister	Not marketed at the moment
DK	Linconsa SA.	Lorat	10 mg	Tablet	Oral use	Blister	Not

Member State	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical Form	Route of administration	Packaging	Package size
	Gran Via Carlos III 98, 7 Planta ES-08028 Barcelona Spain						marketed at the moment
DK	Linconsa SA. Gran Via Carlos III 98, 7 Planta ES-08028 Barcelona Spain	Loratadin "Liconsa"	10 mg	Tablet	Oral use	Blister	Not marketed at the moment
DK	Linconsa SA. Gran Via Carlos III 98, 7 Planta ES-08028 Barcelona Spain	Tifitadin	10 mg	Tablet	Oral use	Blister	Not marketed at the moment
DK	Medis Danmark A/S Havelse Mølle 14 DK-3600 Frederikssund Denmark	Solamed	1 mg/ml	Oral solution	Oral use	Bottle	Not marketed at the moment
DK	Medis Danmark A/S Havelse Mølle 14 DK-3600 Frederikssund Denmark	Delor	10 mg	Tablet	Oral use	Blister	Not marketed at the moment
DK	Medis Danmark A/S, Havelse Mølle 14, DK-3600 Frederikssund Denmark	Loratadin Medis	1mg/ml	Oral suspension	Oral use	Bottle	Ongoing. Packsizes not decided
DK	Medis Danmark A/S, Havelse Mølle 14 DK-3600 Frederikssund Denmark	Loratabs	10 mg	Tablet	Oral use	Blister	Not marketed at the moment
DK	Medis Danmark A/S, Havelse Mølle 14, DK-3600 Frederikssund Denmark	Loarev	1 mg/ml	Oral suspension	Oral use	Bottle	Not marketed at the moment

Member State	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical Form	Route of administration	Packaging	Package size
DK	Medis Danmark A/S, Havelse Mølle 14, DK-3600 Frederikssund Denmark	Lorafluid	1 mg/ml	Oral suspension	Oral use	Bottle	Not marketed at the moment
DK	Medis Danmark A/S, Havelse Mølle 14, DK-3600 Frederikssund Denmark	Loramix	1 mg/ml	Oral suspension	Oral use	Bottle	Not marketed at the moment
DK	Medis Danmark A/S, Havelse Mølle 14, DK-3600 Frederikssund Denmark	Lorfuse	1 mg/ml	Oral suspension	Oral use	Bottle	Not marketed at the moment
DK	Medis Danmark A/S, Havelse Mølle 14, DK-3600 Frederikssund Denmark	Lorasol	1 mg/ml	Oral suspension	Oral use	Bottle	Not marketed at the moment
DK	Medis Danmark A/S, Havelse Mølle 14 DK-3600 Frederikssund Denmark	Deloradin	10 mg	Tablet	Oral use	Blister	Not marketed at the moment
DK	Medis Danmark A/S, Havelse Mølle 14, DK-3600 Frederikssund Denmark	Alerzid	1 mg/ml	Oral suspension	Oral use	Bottle	Not marketed at the moment
DK	NM Pharma A/S. Lautrupvang 8, DK-2750 Ballerup Denmark	Loratadin "NM"	10 mg	Film-coated tablet	Oral use	Blister	10, 30
DK	PharmaCo Dane Marielund vej 46A DK-2730 Herlev Denmark	Loratadin "PCD"	1 mg/ml	Oral suspension	Oral use	Bottle	Not marketed at the moment

Member State	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical Form	Route of administration	Packaging	Package size
DK	Ratiopharm GmbH, Graf-Acro-Strasse 3, D-89079 Ulm, Germany	Loratadin Ratiopharm	10 mg	Tablet	Oral use	Blister	10, 30, 100
DK	Sandoz GmbH Biochemiestrasse 10 A-6250 Kundl Austria	Loratadin Biochemie	10 mg	Tablet	Oral use	Blister	10, 30, 100
DK	Schering Plough Europe Rue de Stalle 73 B-1180 Brussels Belgium	Clarityn	10 mg	Tablet	Oral use	Blister	5, 10, 30, 100
DK	Schering Plough Europe Rue de Stalle 73 B-1180 Brussels Belgium	Clarityn	1 mg/ml	Oral Solution	Oral use	Bottle	1 x 100 ml
DK	Schering Plough Europe Rue de Stalle 73 B-1180 Brussels Belgium	Clarityn	10 mg	Effervescent tablet	Oral use	Blister	10
DK	Schering Plough Europe Rue de Stalle 73 B-1180 Brussels Belgium	Clarityn	10 mg	Oral lyophilisate	Oral use	Blister	Not marketed at the moment
DK	Schering-Plough A/S Hvedemarken 12 DK-3520 Farum Denmark	Versal	10 mg	Tablet	Oral use	Blister	Not marketed at the moment
DK	STADA Arzneimittel AG Stadastrasse 2-18 D-61118 Bad Vilbel Germany	Allergostad	10 mg	Tablet	Oral use	Blister	Not marketed at the moment

Member State	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical Form	Route of administration	Packaging	Package size
DK	STADA Arzneimittel AG Stadastrasse 2-18 D-61118 Bad Vilbel Germany	Loratadin STADA	10 mg	Tablet	Oral use	Blister	10, 30, 50, 100
DK	STADA Arzneimittel AG Stadastrasse 2-18 D-61118 Bad Vilbel Germany	Loradis	10 mg	Tablet	Oral use	Blister	Not marked at the moment
DK	STADA Arzneimittel AG Stadastrasse 2-18 D-61118 Bad Vilbel Germany	Lorapharm	10 mg	Tablet	Oral use	Blister	Not marked at the moment
DK	Sterwin Medicines Ltd 1 Onslow Street, Guildford Surrey GU1 4YS, United Kingdom	Lorafile	10 mg	Tablet	Oral use	Blister	Not marketed at the moment
DK	Wörwag Pharma GmbH & Co. KG. Calwerstrasse 7 D-71034 Böblingen, Germany	LORATAGA MMA	10 mg	Tablet	Oral use	Blister	Not marketed at the moment
FI	A/S Gea Farmaceutisk Fabrik, Holger Danskes Vej 89, DK-2000 Frederiksberg, Denmark	Geklimon	10 mg	Tablet	Oral use	Blister	7, 10, 20, 21, 30, 100
FI	DuraScan Medical Products AS, Svendborgvej 243, DK-5260 Odense S, Denmark	Loratadin Durascan	10 mg	Tablet	Oral use	Blister	5, 7, 10, 14, 20, 30, 40, 100, 105

Member State	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical Form	Route of administration	Packaging	Package size
FI	Generics (UK) Limited, Station Close, Potters Bar, Herts EN6 1TL, United Kingdom	Loratadin Generics	10 mg	Film-coated tablet	Oral use	Blister	5, 7, 10, 14, 15, 20, 21, 30, 50, 100
FI	Laboratoires SMB S.A., Rue de la Pastorale 26-28, B-1080 Brussels, Belgium	Histadin	10 mg	Tablet	Oral use	Blister	10, 30, 100
FI	Ratiopharm GmbH, Graf-Arco-Strasse 3, D-89079 Ulm, Germany	Loratadin-ratiopharm	10 mg	Tablet	Oral use	Blister	2, 7, 10, 20, 30, 50, 100
FI	Sandoz GmbH, Biochemiestrasse 10, A-6250 Kundl, Austria	Loratadin Biochemie	10 mg	Tablet	Oral use	Blister and tablet container	7, 10, 14, 20, 21, 30, 50, 60, 100, 100x1,250
FI	Schering-Plough Europe, 73, Rue De Stalle, B-1180 Brussels, Belgium	Clarityn	1 mg/ml	Oral solution	Oral use	Bottle	120 ml
FI	Schering-Plough Europe, 73, Rue De Stalle, B-1180 Brussels, Belgium	Clarityn	10 mg	Tablet	Oral use	Blister	10, 30, 100
FI	Schering-Plough Europe, 73, Rue De Stalle, B-1180 Brussels, Belgium	Clarityn-S	10 mg	Oral lyophilisate	Oral use	Blister	8, 10, 30, 100,

Member State	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical Form	Route of administration	Packaging	Package size
FI	STADA Arzneimittel AG, Stadastrasse 2-18, D-61118 Bad Vilbel, Germany	Loratadin Stada	10 mg	Tablet	Oral use	Blister	1, 5, 7, 10, 14, 15, 20, 21, 30, 50, 60, 90, 100, 250
FI	STADA Arzneimittel AG, Stadastrasse 2-18, D-61118 Bad Vilbel, Germany	Loratadin Stada	1 mg/ml	Oral solution	Oral use	Bottle	50, 60, 100, 120, 150 ml
FI	Verman Oy Ab, Vanhankyläntie 44 B, FIN-04401 Järvenpää, Finland	Tuulix	10 mg	Tablet	Oral use	Blister	1, 10, 30, 100
FI	Verman Oy Ab, Vanhankyläntie 44 B, FIN-04401 Järvenpää, Finland	Tuulix	1 mg/ml	Oral solution	Oral use	Bottle	60, 100, 200 ml
FR	ENDWELL Elm House Ashbourne Industrial Estate Ashbourne - County Meath Ireland	LORATADINE ENDWELL	10 mg	Tablet	Oral use	Blister (PVC/Alu)	15, 28, 30, 100
FR	Generics 28 Station Close Potters Bar EN6 1TL Hertfordshire, United Kingdom	LORATADINE	10 mg	Film-coated tablet	Oral use	Blister (PVC/Alu)	5, 7, 10, 14, 15

Member State	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical Form	Route of administration	Packaging	Package size
FR	MADAUS Immeuble Mercure III 55 bis, Quai de Grenelle F-75015 Paris, France	LORATADINE MADAUS	10 mg	Tablets	Oral use	Blister (PVC/Alu)	15, 28, 30
FR	Schering Plough 92, rue Baudin F-92307 Levallois Perret Cedex, France	CLARITYNE	0.1 g/100ml	Syrup	Oral use	Glass (brown)	60, 120 ml
FR	Schering Plough 92, rue Baudin F-92307 Levallois Perret Cedex, France	CLARITYNE	10 mg	Tablet	Oral use	Blister (PVC/Alu)	10, 15, 20
FR	Schering Plough 92, rue Baudin F-92307 Levallois Perret Cedex, France	CLARITYNE	10 mg	Effervescent tablet	Oral use	Blister (Alu/Alu)	7, 10, 14, 15, 20, 21, 30
FR	Schering Plough 92, rue Baudin F-92307 Levallois Perret Cedex, France	LORATADINE SCHERING PLOUGH	0.10 %	Syrup	Oral use	Bottle (glass)	60, 125ml
FR	Schering Plough 92, rue Baudin F-92307 Levallois Perret Cedex, France	LORATADINE SCHERING PLOUGH	10 mg	Effervescent tablet	Oral use	Blister (Alu/Alu)	7, 10, 14, 15, 20, 21, 30
FR	Schering Plough 92, rue Baudin F-92307 Levallois Perret Cedex, France	LORATADINE SCHERING PLOUGH	10 mg	Tablet	Oral use	Blister (PVC/Alu)	10, 15, 20
FR	Schering Plough 92, rue Baudin F-92307 Levallois Perret Cedex, France	VIARO	10 mg	Tablet	Oral use	Blister (PVC/Alu)	5, 7, 10, 15

Member State	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical Form	Route of administration	Packaging	Package size
GE	1 A Pharma GmbH Keltenring 1+3 D-82041 Oberaching Germany	Loratad 10 mg	10 mg	Tablet	Oral use	Blister (PVC/Alu)	7, 20, 50, 100
GE	1 A Pharma GmbH Keltenring 1 + 3 D-82041 Oberhaching Germany	Loratad 10	10 mg	Tablet	Oral use	Blister (PVC/Alu)	7, 10, 14, 20, 21, 30, 50, 100
GE	1 A Pharma GmbH Keltenring 1 + 3 D-82041 Oberhaching Germany	Loratadin-1A Pharma	10 mg	Tablet	Oral use	Blister (PVC/Alu)	20, 30, 50, 100
GE	Acis Arzneimittel Vertrieb AG Bajuwarenring 14 D-82041 Oberhachling Germany	Loratadin Acis 10 mg	10 mg	Tablet	Oral use	Blister (PVC/PVDC/Alu)	20, 50, 100
GE	Alfred E.Tiefenbacher GmbH & Co. Van-der-Schmissen-Str 1 D-22767 Hamburg Germany	Chemotadin 10 mg Tabletten	10 mg	Tablet	Oral use	Blister (PVC/Alu)	7, 10, 20, 30, 50, 100
GE	Alfred E.Tiefenbacher GmbH & Co. Van-der-Schmissen-Str 1 D-22767 Hamburg Germany	Lorat 10 mg Tabletten	10 mg	Tablet	Oral use	Blister (PVC/Alu)	7, 10, 20, 30, 50, 100
GE	Aliud Pharma GmbH & Co KG Gottlieb-Daimler Str 19 D-89150 Laichingen Germany	Loratadin AL 10 mg Tabletten	10 mg	Tablet	Oral use	Blister (PVC/Alu)	7, 20, 50, 100

Member State	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical Form	Route of administration	Packaging	Package size
GE	Aliud Pharma GmbH & Co KG Gottlieb-Daimler Str 19 D-89150 Laichingen Germany	Loratadin AL 1 1 mg/ml saft	1 mg/1ml	Syrup	Oral use	Bottle (PE)	50, 60, 100, 120, 150 ml
GE	Alpharma-ISIS GmbH & Co KG Elisabeth-Selbert-Str. 1 D-40764 Langenfeld Germany	LORA-PUREN	10 mg	Tablet	Oral use	Blister (PVC/Alu)	7, 10, 20, 50, 100, 500
GE	Altana Consumer Health GmbH Bargkoppelweg 66 D-22145 Hamburg Germany	Enatin	10 mg	Tablet	Oral use	Blister (PVC/Alu)	10, 20, 50, 100
GE	AWD.pharma GmbH & Co. KG Leipziger Str. 7-13 D-01097 Dresden Germany	Loralerg	10 mg	Tablet	Oral use	Blister (PVC/Alu)	7, 20, 50, 100, 500
GE	Basics GmbH Hemmelrather Weg 201 D-51377 Leverkusen Germany	!LORA BASICS	10 mg	Tablet	Oral use	Blister (PVC/Alu)	7, 20, 50, 100
GE	BC Biochemie Carl-Zeiss-Ring 3 D-85737 Ismaning Germany	TRILOR 10 mg Tabletten	10 mg	Tablet	Oral use	Blister (PVC/AL, PVC/AL/PVDC,PVC/PE,PVDC/AL)	7, 10, 20, 50, 100
GE	Betapharm Arzneimittel GmbH Kobelweg 95 D-86156 Augsburg Germany	Betalora 10	10 mg	Tablet	Oral use	Blister (PVC/Alu)	7, 10, 20, 30, 50, 100

Member State	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical Form	Route of administration	Packaging	Package size
GE	Betapharm Arzneimittel GmbH Kobelweg 95 D-86156 Augsburg Germany	Lobeta gegen Allergien	10 mg	Tablet	Oral use	Blister (PVC/Alu)	7, 20, 50, 100
GE	ct-Arzneimittel GmbH Lengeder Str. 42a D-13407 Berlin Germany	Loratadin von ct	10 mg	Tablet	Oral use	Blister (PVC/Alu)	7, 20, 50, 100
GE	ct-Arzneimittel GmbH Lengeder Str. 42a D-13407 Berlin Germany	Loratadin von ct	10 mg	Tablet	Oral use	Blister (PVC/PVDC/Alu)	7, 20, 50, 100
GE	Dermapharm AG Luise-Ullrich-Str. 6 D-82031 Gruenwald Germany	Loraderm	10 mg	Tablet	Oral use	Blister (PVC/Alu)	7, 20, 50, 100
GE	Dr.August Wolff GmbH & Co. Arzneimittel Sudbrackstr. 56 D-33611 Bielefeld Germany	Loradino 10 mg Tabletten	10 mg	Tablet	Oral use	Blister (PVC/Alu)	7, 20, 50, 100
GE	Dr.Gerhard Mann Chem.-pharm.Fabrik GmbH Brunsbuetteler Damm 165-173 D-13581 Berlin Germany	Lora Rhinol 10 mg Tabletten	10 mg	Tablet	Oral use	Blister (PVC/Alu)	7, 20, 50, 100
GE	Dr.Gerhard Mann Chem.-pharm.Fabrik GmbH Brunsbuetteler Damm 165-173, D-13581 Berlin Germany	Vividrin Tabletten Wirkstoff Loratadin	10 mg	Tablet	Oral use	Blister (Alu)	7, 14, 28, 56

Member State	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical Form	Route of administration	Packaging	Package size
GE	Dr.R.Pfleger Chemische Fabrik GmbH Emil-Kemmer-Str. 33 D-96103 Hallstadt Germany	Lantamed 10 mg Tabletten	10 mg	Tablet	Oral use	Blister (PVC/Alu)	7, 20, 50, 100
GE	Essex Pharma GmbH Thomas-Dehler-Str. 27 D-81737 Muenchen Germany	Lisino	10 mg	Tablet	Oral use	Blister	20, 50, 100
GE	Essex Pharma GmbH Thomas-Dehler-Str. 27 D-81737 Muenchen Germany	Lisino Brause Brausetabletten	10 mg	Effervescent tablet	Oral use	Blister	10, 30
GE	Essex Pharma GmbH Thomas-Dehler-Str. 27 D-81737 Muenchen Germany	Lisino extra schnellaufloesende Tabletten	10 mg	Tablet	Oral use	Blister	8, 10, 20, 50, 60
GE	Essex Pharma GmbH Thomas-Dehler-Str. 27 D-81737 Muenchen Germany	Lisino S	10 mg	Tablet	Oral use	Blister	7
GE	Essex Pharma GmbH Thomas-Dehler-Str. 27 D-81737 Muenchen Germany	Loratadin Brause Brausetabletten	10 mg	Effervescent tablet	Oral use	Blister	10
GE	GALENpharma GmbH Wittland 13 D-24109 Kiel Germany	LORAGALEN	10 mg	Tablet	Oral use	Blister (PVC/Alu)	7, 20, 50, 100, 500

Member State	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical Form	Route of administration	Packaging	Package size
GE	Hermal Kurt Herrmann GmbH & Co. Scholtzstr. 3 D-21465 Reinbek Germany	Loratadindura 10 mg Filmtabletten	10 mg	Tablet	Oral use	Blister strips (PVC/Alu)	7, 20, 50, 100
GE	Heumann Pharma GmbH Suedwestpark 50 D-90449 Nuernberg Germany	Loratadin 10 Heumann	10 mg	Tablet	Oral use	Blister (PVC/Alu)	7, 20, 50, 100, 500
GE	HEXAL AG Industriestr. 25 D-83607 Holzkirchen Germany	Loratadina 10 mg	10 mg	Tablet	Oral use	Blister (PVC/Alu)	7, 20, 50, 100
GE	HEXAL AG Industriestr. 25 D-83607 Holzkirchen Germany	Lorano	10 mg	Tablet	Oral use	Blister (PVC/Alu)	7, 10, 20, 30, 50, 100
GE	HEXAL AG Industriestr. 25 D-83607 Holzkirchen Germany	Lorano akut	10 mg	Tablet	Oral use	Blister (PVC/Alu)	7, 14, 20, 50, 100
GE	Krewel Meuselbach GmbH Krewelstr. 25 D-3783 Eitorf Germany	Loraclar	10 mg	Tablet	Oral use	Blister (PVC/Alu)	7, 20, 50, 100, 500
GE	KSK – Pharma Vertriebs AG Roggenbackstr. 4 D-76133 Karlsruhe Germany	Loratadin KSK	10 mg	Tablet	Oral use	Blister (PVC/Alu)	7, 20, 30, 50, 100

Member State	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical Form	Route of administration	Packaging	Package size
GE	Lichtenstein Pharmazeutica GmbH & Co. Industriestr. 26 D-56218 Muelheim-Kaerlich Germany	Lora-Lich 10 mg Tabletten	10 mg	Tablet	Oral use	Blister (PVC/Alu)	7, 20, 50, 100
GE	Lindopharm GmbH Neustr. 82 D-40721 Hilden Germany	Loravis 10 mg Tabletten	10 mg	Tablet	Oral use	Blister (PVC/Alu)	7, 20, 50, 100
GE	Medis Danmark A/S Havelse Mølle 14 DK-3600 Fredrikssund Denmark	Alerisa	10 mg	Tablet	Oral use	Blister (PVC/Alu)	7, 10, 14, 20, 50, 100
GE	PROMEDIPHARM GmbH Berliner Ring 89 D-64625 Bensheim Germany	Lorasan	10 mg	Tablet	Oral use	Blister (PVC/Alu)	7, 20, 50, 100, 500
GE	PROMEDIPHARM GmbH Berliner Ring 89 D-64625 Bensheim Germany	Loratadura 10mg	10 mg	Tablet	Oral use	Blister (PVC/Alu)	7, 20, 50, 100, 500
GE	Ratiopharm GmbH Graf-Arco-Str. 3 D-89079 Ulm Germany	Lora-ratiopharm 10 mg Tabletten	10 mg	Tablet	Oral use	Blister (PVC/Alu)	20, 50, 100
GE	Ratiopharm GmbH Graf-Arco-Str. 3 D-89079 Ulm Germany	Loratadin-ratiopharm 10 mg Tabletten	10 mg	Tablet	Oral use	Blister (PVC/Alu)	7, 20, 50, 100

Member State	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical Form	Route of administration	Packaging	Package size
GE	Ratiopharm GmbH Graf-Arco-Str. 3 D-89079 Ulm Germany	Loratadin-ratiopharm (10 mg Tabletten) bei Allergien	10 mg	Tablet	Oral use	Blister (PVC/PVDC/Alu)	20, 50, 100
GE	Ratiopharm GmbH Graf-Arco-Str. 3 D-89079 Ulm Germany	Loratadinum von ratio 10 mg Tabletten	10 mg	Tablet	Oral use	Blister (PVC/PVDC/Alu)	20, 50, 100
GE	Sandoz Pharmaceutical GmbH Carl-Zeiss-Ring D-85737 Ismaning Germany	Loratadin Sandoz 10mg Tabletten	10 mg	Tablet	Oral use	Blister (PVC/Alu)	7, 10, 20, 50, 100
GE	Sandoz Pharmaceutical GmbH Carl-Zeiss-Ring D-85737 Ismaning Germany	Loratadin Sandoz 10 mg Tabletten	10 mg	Tablet	Oral use	Blister (PVC/AL, PVC/AL/PVDC,PVC/PE,PVDC/AL)	7, 10, 20, 50, 100
GE	Stadapharm GmbH Stadastr. 2-18 D-61118 Bad Vilbel Germany	Loratadin STADA allerg 10 mg Tabletten	10 mg	Tablet	Oral use	Blister (PVC/Alu)	7, 20, 50, 100
GE	Woelm Pharma GmbH & Co. Rhoendorfer Str. 80 D-53604 Bad Honnef Germany	Livotab direkt Tabletten	10 mg	Tablet	Oral use	Blister (PVC/Alu)	7, 10, 14, 28
GE	Woerwag Pharma GmbH & Co. Calwer Str. 7 D-71034 Boeblingen Germany	Loragamma 10 mg Tabletten	10 mg	Tablet	Oral use	Blister (PVC/Alu)	7, 10, 20, 50, 100

Member State	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical Form	Route of administration	Packaging	Package size
GR	ΑΝΦΑΡΜ ΕΛΛΑΣ Α.Ε. 442 Acharnon Str GR-11143 Athens Greece	Latoren	10 mg	Tablet	Oral use	Blister	14, 28
GR	Biomedica-Chemica S.A. Liolios-Parodos G. Lyra 25-K. Kifisia, Greece	Zelmar	10 mg	Tablet	Oral use	Blister	14, 21
GR	BIOSPRAY S.A. 39, Favierou str. GR-104 38 Athens Greece	Loratab	10 mg	Tablet	Oral use	Blister	14, 21, 42
GR	Coup OE Kouparousos Ag. Barbaras 53, GR-172 35 Dafni Greece	Ralinet	10 mg	Tablet	Oral use	Blister	14, 21
GR	DOCTUM S.A. 5, Dorilaiou str. GR-115 21 Athens Greece	Allergofact	10 mg	Tablet	Oral use	Blister	14, 20
GR	Faran ABEE Ahaias kai Trizinias 145 64 N. Kifisia, Greece	Difmedol	10 mg	Tablet	Oral use	Blister	14
GR	Finixfarm Ant. Polyxronis Anabrytis 11 Athens, Greece	Lora	10 mg	Tablet	Oral use	Blister	14, 21, 28

Member State	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical Form	Route of administration	Packaging	Package size
GR	HELP ABEE 4 Valaoritou Str GR-14452 Metamorphosi Greece	Helporigin	10 mg	Tablet	Oral use	Blister	14
GR	KLEVA E.Π.E. 189 Parnithos Ave GR-13671 Acharnai Greece	Horestyl	10 mg	Tablet	Oral use	Blister	14, 21
GR	KLEVA E.Π.E. 189 Parnithos Ave GR-13671 Acharnai Greece	Horestyl	5 mg/ 5 ml	Syrup	Oral use	Bottle	120 ml
GR	LAMDA PHARMACEUTICAL 6 Thermopilon str. 152 33 Chalandri Athens Greece	Loralerg	10 mg	Effervescent tablet	Oral use	Blister	21
GR	LEOVAN Pharmaceuticals 22 Argonafton Argyroupoli T.K. 16452 Athens Greece	Ristotadin	10 mg	Tablet	Oral use	Blister	21
GR	MED-ONE S.A. ΕΛΛΑΣ 211 Parnithos Ave GR-13671 Acharnal Athens Greece	Allerdrug	5 mg/5 ml	Syrup	Oral use	Bottle	120 ml

Member State	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical Form	Route of administration	Packaging	Package size
GR	MED-ONE S.A. ΕΛΛΑΣ 211 Parnithos Ave GR-13671 Acharnal Athens Greece	Allerdrug	10 mg	Tablet	Oral use	Blister	14
GR	Novartis (Hellas) A.E.B.E 120 xlm Ethnikis Odou Athinon-Lamias GR-14410 Metamorfosi Greece	Loratadine/Biochemie	10 mg	Tablet	Oral use	Blister (PVC/AL, PVC/PE, PVC)	7, 10, 14, 20, 21, 30, 50, 60, 100x1, 100, 250 (PVC/AL) 7 (PVC/PE) 10, 14, 20, 21, 30, 50, 60, 100x1, 100, 250 (PVC)
GR	Novexal Hellas 25 AgDimitriou Str 174 55 Kalamaki, Athens Greece	Loratadine / Novexal	5 mg/5 ml	Syrup	Oral use	Bottle	120 ml
GR	Novexal Hellas 25 AgDimitriou Str 174 55 Kalamaki, Athens Greece	Loratadine / Novexal	10 mg	tablet	Oral use	Blister	14

Member State	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical Form	Route of administration	Packaging	Package size
GR	Relyo Hellas ΕΠΕ Pan. Kabbadas Fabicrou 48 Athens, Greece	Novacloxab	10 mg	Tablet	Oral use	Blister	10, 14
GR	Schering Plough A.Φ.B.E.E. 63 Agiou Dimitriou GR-17456 Alimos Greece	Clarityne	10 mg	Tablet	Oral use	Blister	10, 14, 21
GR	Schering Plough A.Φ.B.E.E. 63 Agiou Dimitriou GR-17456 Alimos Greece	Clarityne	5 mg/5 ml	Syrup	Oral use	Bottle	120 ml
GR	Schering Plough A.Φ.B.E.E. 63 Agiou Dimitriou GR-17456 Alimos Greece	Clarityne	10 mg	Effervescent tablet	Oral use	Blister	10, 21
GR	Schering Plough A.Φ.B.E.E. 63 Agiou Dimitriou GR-17456 Alimos Greece	Clarityne	10 mg	Oral lyophilisate	Oral use	Blister	10, 20
GR	VELKA HELLAS AEBE 12 Korinthou str. 154 51 Psychiko Athens Greece	Igir	10 mg	Tablet	Oral use	Blister	21
GR	VIOFAR EPE Terma Evaggelistrias GR-136 71 Acharnai Athens Greece	Bollinol	10 mg	Tablet	Oral use	Blister	20

Member State	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical Form	Route of administration	Packaging	Package size
GR	VIOFAR EPE Terma Evaggelistrias GR-136 71 Acharnai Athens Greece	Bollinol	5 mg/5 ml	Syrup	Oral use	Bottle	120 ml
GR	ΦΑΡΜΑΤΕΝ Ε.Π.Ε 68 Menandrou Str GR-10432 Athens Greece	Biliranin	10 mg	Tablet	Oral use	Blister	14
GR	ΦΑΡΜΕΞ Α.Ε. 156 Aylonos Str Sepolia GR-1044 Greece	Utel	10 mg	Tablet	Oral use	Blister	10, 14, 21
GR	ΦΑΡΜΕΞ Α.Ε. 156 Aylonos Str Sepolia GR-1044 Greece	Utel	5 mg/5 ml	Syrup	Oral use	Bottle	120 ml
IC	Delta hf. Reykjavíkurvegi 78 IS-220 Hafnarfjörður Ísland	Lóritín	10 mg	Tablet	Oral use	Blister	10, 30, 100
IC	NM Pharma, Reykjavíkurvegi 78 IS-220 Hafnarfjörður Ísland	Loratadine NM Pharma	10 mg	Tablet	Oral use	Blister	10, 30, 100
IC	Schering-Plough Europe, Rue de Stalle, B-1180 Brussels Belgium	Clarityn	10 mg	Effervescent tablet	Oral use	Blister	10

Member State	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical Form	Route of administration	Packaging	Package size
IC	Schering-Plough Europe, Rue de Stalle, B-1180 Brussels Belgium	Clarityn	1 mg/ml	Oral solution	Oral use	Bottle	100 ml
IC	Schering-Plough Europe, Rue de Stalle, B-1180 Brussels Belgium	Clarityn	10 mg	Tablet	Oral use	Blister	10, 30, 100
IR	McDermott Laboratories Ltd 35 Baldoyle Industrial Estate, Grange Road Baldoyle Dublin 13, Ireland	Histaclar	10 mg	Tablet	Oral use	Blister	5, 7, 10, 14, 15, 20, 21, 30, 50, 100
IR	McDermott Laboratories Ltd 35 Baldoyle Industrial Estate, Grange Road Baldoyle Dublin 13, Ireland	Histaclar Allergy Tablet	10 mg	Tablet	Oral use	Blister	5, 7, 10, 14, 15, 20, 21, 30, 50, 100
IR	Olinka UK Ltd 38-40 Chamberlayne Road London, NW10 3JE, United Kingdom	Loratadine	10 mg	Tablet	Oral use	Blister	7, 10, 14, 28, 30, 56, 60, 84, 90, 100, 120, 150
IR	Schering-Plough Ltd Schering-Plough House Shire Park Welwyn Garden City Hertfordshire, AL7 1TW, United Kingdom	Clarityn	10 mg	Tablet	Oral use	Blister	5, 7, 10, 30

Member State	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical Form	Route of administration	Packaging	Package size
IR	Schering-Plough Ltd Schering-Plough House Shire Park Welwyn Garden City Hertfordshire, AL7 1TW, United Kingdom	Clarityn	1 mg/ ml	Syrup	Oral use	Bottle (glass)	100, 200ml
IR	Schering-Plough Ltd Schering-Plough House Shire Park Welwyn Garden City Hertfordshire, AL7 1TW, United Kingdom	Clarityn Rapide	10 mg	Tablet	Oral use	Strip	30
IR	Schering-Plough Ltd Schering-Plough House Shire Park Welwyn Garden City Hertfordshire, AL7 1TW, United Kingdom	Clarityn Rapide Allergy Tablets	10 mg	Tablet	Oral use	Strip	7, 10
IT	Essex Italia SPA Via Serio, 1 I-20139 Milano, Italy	Alorin	10 mg	Tablet	Oral use	Blister	5, 7, 10, 20
IT	Essex Italia SPA Via Serio, 1 I-20139 Milano, Italy	Alorin	1 mg/ml	Oral solution	Oral use	Bottle	100 ml
IT	Essex Italia SPA Via Serio, 1 I-20139 Milano, Italy	Alorin	10 mg	Effervescent tablet	Oral use	Blister	20

Member State	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical Form	Route of administration	Packaging	Package size
IT	Essex Italia SPA Via Serio, 1 I-20139 Milano, Italy	Alorin	10 mg	Oral lyophilisate	Oral use	Blister	20
IT	F.I.R.M.A. SPA Via Dio Scandicci, 37 I-50143 Firenze, Italy	Fristamin	10 mg	Tablet	Oral use	Blister	5, 7, 10, 20
IT	F.I.R.M.A. SPA Via Dio Scandicci, 37 I-50143 Firenze, Italy	Fristamin	1 mg/ml	Oral solution	Oral use	Bottle	100 ml
IT	F.I.R.M.A. SPA Via Dio Scandicci, 37 I-50143 Firenze, Italy	Fristamin	10 mg	Effervescent tablet	Oral use	Blister	20
IT	F.I.R.M.A. SPA Via Dio Scandicci, 37 I-50143 Firenze, Italy	Fristamin	10 mg	Oral lyophilisate	Oral use	Blister	20
IT	Schering Plough SPA Via Ripamonti, 89 I-20141 Milano, Italy	Clarityn	10 mg	Tablet	Oral use	Blister	5, 7, 10, 20
IT	Schering Plough SPA Via Ripamonti, 89 I-20141 Milano, Italy	Clarityn	1mg/ml	Oral Solution	Oral use	Bottle	100 ml
IT	Schering Plough SPA Via Ripamonti, 89 I-20141 Milano, Italy	Clarityn	10 mg	Effervescent tablet	Oral use	Blister	20

Member State	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical Form	Route of administration	Packaging	Package size
IT	Schering Plough SPA Via Ripamonti, 89 I-20141 Milano, Italy	Clarityn	10 mg	Oral lyophilisate	Oral use	Blister	20
LU	Merck s.a., Brusselsesteenweg 288, B-3090 Overijse, Belgium	Merck-Loratadine	10 mg	Tablet	Oral use	Blister (PVC/AL)	5, 7, 10, 14, 15, 20, 21, 30, 50, 100
LU	Ratiopharm GmbH Graf-Arco-Strasse 3 D-89079 Ulm, Germany	Loratadine Ratiopharm	10 mg	Tablet	Oral use	Blister (PVC/Al)	7, 20, 50, 100
LU	SCHERING-PLOUGH s.a. 73, Rue de Stalle B-1180 Brussels, Belgium	Claritine	10 mg	Effervescent tablet	Oral use	Blister	10, 21
LU	SCHERING-PLOUGH s.a. 73, Rue de Stalle B-1180 Brussels, Belgium	Claritine	10 mg	Tablet	Oral use	Blister	7, 21
LU	SCHERING-PLOUGH s.a. 73, Rue de Stalle B-1180 Brussels, Belgium	Claritine Pédiatrique	1 mg/ ml	Syrup	Oral use	Bottle	100 ml
LU	SCHERING-PLOUGH s.a. 73, Rue de Stalle B-1180 Brussels, Belgium	Sanelor	10 mg	Tablet	Oral use	Blister	10

Member State	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical Form	Route of administration	Packaging	Package size
NL	Centrafarm Services B.V. Postbus 289 NL-4870 AG Ehen-Leur Netherlands	Loratadine CF 1 mg/ml	1 mg/ml	Syrup	Oral use	Bottle	50, 60, 100, 120, 150 ml
NL	Centrafarm Services B.V. Postbus 289 NL-4870 AG Etten-Leur Netherlands	Loratadine CF 10 mg	10 mg	Tablet	Oral use	Blister	1, 5, 7, 10, 14, 15, 20, 21, 30, 50, 60, 90, 100, 250
NL	Disphar International B.V. Postbus 100 NL-7255 ZK Hengelo (Gld), Netherlands	Loratadine Disphar 10	10 mg	Tablet	Oral use	Blister	30
NL	Genfarma B.V. P.O. Box 2062 NL-1500 GB Zaandam Netherlands	Loratadine Gf 10 mg	10 mg	Tablet	Oral use	Blister	7, 10, 20, 21, 30, 50, 100
NL	Hexal Pharma Nederland B.V. Postbus 251 NL-2180 AG Hillegom, Netherlands	Loratadine 10 mg Hexal	10 mg	Tablet	Oral use	Blister	7, 10, 20, 21, 30, 100
NL	Katwijk Farma B.V. Postbus 408 NL-2300 AK Leiden, Netherlands	Loratadine 1mg/ml Katwijk	1 mg/ml	Syrup	Oral use	Bottle	60, 120 ml
NL	Katwijk Farma B.V. Postbus 408 NL-2300 AK Leiden, Netherlands	Loratadine 10 mg Katwijk	10 mg	Tablet	Oral use	Blister	10, 30, 250

Member State	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical Form	Route of administration	Packaging	Package size
NL	Merck Generics B.V. Dieselweg 26 NL 3752 LB Bunschoten Netherlands	Loratadine Merck 10 mg	10 mg	Tablet	Oral use	Blister	5, 7, 10, 14, 15, 20, 21, 30, 50, 100
NL	Multipharma B.V. Postbus 216 NL-1380 AE Weesp, Netherlands	Loratadine 10	10 mg	Tablet	Oral use	Blister	7, 10, 20, 50, 100, 250
NL	Multipharma B.V. Postbus 216 NL-1380 AE Weesp, Netherlands	MP-Loratadine	10 mg	Tablet	Oral use	Blister	7, 10, 14, 20, 21, 30, 50, 60, 100, 250
NL	Schering-Plough B.V. Postbus 1364 NL-3600 BJ Maarssen, Netherlands	Claritine Reditabs	10 mg	Oral Lyophilisate	Oral use	Blister	10, 20, 30
NL	Schering-Plough B.V. Postbus 1364 NL-3600 BJ Maarssen, Netherlands	Claritine	1 mg/ml	Syrup	Oral use	Bottle	60, 120 ml
NL	Schering-Plough B.V. Postbus 1364 NL-3600 BJ Maarssen, Netherlands	Claritine	10 mg	Tablet	Oral use	Blister	2, 5, 7, 10, 30
NL	Schering-Plough B.V. Postbus 1364 NL-3600 BJ Maarssen, Netherlands	Claritine	10 mg	Effervescent tablet	Oral use	Blister	7, 10, 30

Member State	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical Form	Route of administration	Packaging	Package size
NL	Schering-Plough B.V. Postbus 1364 NL-3600 BJ Maarssen, Netherlands	Sanelor	10 mg	Tablet	Oral use	Blister	10
NL	Stada Arzneimittel AG Stadastrasse 2-18 D-61118 Bad Vilbel, Germany	Lorastad 1 mg/ml	1 mg/ml	Syrup	Oral use	Bottle	50, 60, 100, 120, 150 ml
NL	Stada Arzneimittel AG Stadastrasse 2-18 D-61118 Bad Vilbel, Germany	Lorastad 10 mg	10 mg	Tablet	Oral use	Blister	1, 5, 7, 10, 14, 15, 20, 21, 30, 50, 60, 90, 100, 250
NO	A/S GEA Farmaceutisk Fabrik, Holger Danskes vej 89, DK-2000 Frederiksberg, Denmark	Loratadin Gea	10 mg	Tablet	Oral use	Blister	7, 10, 20, 21, 30, 100
NO	Sandoz GmbH, Biochemiestrasse 10, A-6250 Kundl, Austria	Loraratidin Biochemie	10 mg	Tablet	Oral use	Blister	7, 10, 14, 20, 21, 30, 50, 60, 100, 100x1, 250
NO	Duranor AS, Hoffsv. 70 B, N-0319 Oslo, Norway	Loratadin Duranor	10 mg	Tablet	Oral use	Blister	5, 7, 10, 14, 20, 30, 40, 100, 105

Member State	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical Form	Route of administration	Packaging	Package size
NO	NM Pharma AS, Lilleakerv. 2 B, N-0283 Oslo, Norway	Loratadin	10 mg	Tablet	Oral use	Blister	5, 7, 10, 14, 15, 20, 21, 30, 50, 100
NO	Ratiopharm GmbH, Graf-Arco-Str 3, DE-89079 Ulm, Germany	Loratadin Ratiopharm	10 mg	Tablet	Oral use	Blister	2, 7, 10, 20, 20x1, 21, 30, 50, 100, 100x1
NO	Schering-Plough AS, Ankerveien 209, N-1359 Eiksmarka, Norway	Versal	10 mg	Tablet	Oral use	Blister	10, 30, 60, 100
NO	Schering-Plough Europe, 73, Rue de Stalle, B-1180 Brussels, Belgium	Clarityn	1 mg/ml	Oral solution	Oral use	Bottle	120 ml
NO	Schering-Plough Europe, 73, Rue de Stalle, B-1180 Brussels, Belgium	Clarityn	10 mg	Tablet	Oral use	Blister	7, 30, 100
NO	Schering-Plough Europe, 73, Rue de Stalle, B-1180 Brussels, Belgium	Clarityn-S	10 mg	Oral lyophilisate	Oral use	Blister	10, 30, 100
NO	Stada Arzneimittel AG, Stadastrasse 2-18. D-61118 Bad Vilbel, Germany	Loratadin Stada	1 mg/ml	Oral solution	Oral use	Bottle	50, 60, 100, 120, 150 ml

Member State	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical Form	Route of administration	Packaging	Package size
NO	Stada Arzneimittel AG, Stadastrasse 2-18. D-61118 Bad Vilbel, Germany	Loratadin Stada	10 mg	Tablet	Oral use	Blister	10, 20, 28, 30, 50, 56, 60, 90, 100
PT	Decomed Farmacêutica, S.A. Rua Sebastião e Silva, 56 P-2745-838 Massamá Portugal	Loratin	10 mg	Tablet	Oral use	Blister	20
PT	Euro-Labor, Laboratórios de Síntese Química e Especialidades Farmacêuticas, S.A. Rua Alfredo da Silva, 16 P.º Box 60270 P-2720-028 Amadora Portugal	Loristine	10 mg	Tablet	Oral use	Blister	20
PT	Farmalavi - Produtos Farmacêuticos, Sociedade Unipessoal, Lda. Rua Elias Garcia, 28 Venda Nova P-2700-327 Amadora Portugal	Loratadina Farmalavi 10 mg comprimidos	10 mg	Tablet	Oral use	Blister	20
PT	Farmoz - Sociedade Técnico-Medicinal, S.A. Rua Prof. Henrique de Barros, Edifício Sagres, 3ºA P-2685-338 Prior Velho Portugal	Evertine	10 mg	Tablet	Oral use	Blister	10, 20

Member State	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical Form	Route of administration	Packaging	Package size
PT	Farmoz - Sociedade Técnico-Medicinal, S.A. Rua Prof. Henrique de Barros, Edifício Sagres, 3ºA P-2685-338 Prior Velho Portugal	Evertine	1 mg/ml	Syrup	Oral use	Bottle	100ml
PT	Generis Farmacêutica, S.A. Rua José Galhardo, n.º 3 P-1750-131 Lisboa Portugal	Loratadina Generis 10 mg Comprimidos	10 mg	Tablet	Oral use	Blister	20
PT	Irex - Promoção e Comercialização de Produtos Farmacêuticos, Lda Praça Duque de Saldanha n° 1-4°E P-1050-094 Lisboa Portugal	Loratadina Irex 10 mg comprimidos	10 mg	Tablet	Oral use	Blister	7, 20, 50, 100
PT	Labesfal - Laboratórios Almiro, S.A. , Avenida Dr Afonso Costa P-3465-051 Campo de Besteiros Portugal	Loratadina Labesfal 10 mg Comprimidos	10 mg	Tablet	Oral use	Blister	20
PT	Labesfal - Laboratórios Almiro, S.A. Avenida Dr Afonso Costa Apartado 7 P-3465-051 Campo de Besteiros Portugal	Crizin	10 mg	Tablet	Oral use	Blister	20
PT	Merck Genéricos - Produtos Farmacêuticos, Lda. Rua Alfredo da Silva, 3 - C - 4º P-1300-040 Lisboa Portugal	Loratadina Merck Genéricos 10 mg Comprimidos Revestidos	10 mg	Coated tablet	Oral use	Blister	5, 7, 10, 14, 15, 20, 21, 30, 50, 100

Member State	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical Form	Route of administration	Packaging	Package size
PT	Pentafarma - Sociedade Técnico-Medicinal, S.A. Rua Prof. Henrique de Barros, Edif. Sagres, 5ºA P-2685-338 Prior Velho Portugal	Zolargene	10 mg	Tablet	Oral use	Blister	10, 20
PT	Pentafarma - Sociedade Técnico-Medicinal, S.A. Rua Prof. Henrique de Barros, Edif. Sagres, 5ºA P-2685-338 Prior Velho Portugal	Zolargene	1 mg/ml	Syrup	Oral use	Bottle	100 ml
PT	Plough Farma, Lda. Rua Agualva dos Açores nº 16 P-2735-557 Agualva - Cacém Portugal	Alertrin	10 mg	Tablet	Oral use	Blister	10, 20
PT	Plough Farma, Lda. Rua Agualva dos Açores nº 16 P-2735-557 Agualva - Cacém Portugal	Alertrin	10 mg	Effervescent tablet	Oral use	Blister	10, 20

Member State	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical Form	Route of administration	Packaging	Package size
PT	Plough Farma, Lda. Rua Agualva dos Açores nº 16 P-2735-557 Agualva - Cacém Portugal	Alertrin Zydis	10 mg	Oral lyophilisate	Oral use	Blister	10, 20
PT	Plough Farma, Lda. Rua Agualva dos Açores nº 16 P-2735-557 Agualva - Cacém Portugal	Alertrin	1mg/ml	Syrup	Oral use	Bottle	100, 200ml
PT	Produfarma, Lda. (Laboratório Scientia) Estrada de Benfica, 403-B P-1500-077 Lisboa Portugal	Alerdaune	10 mg	Tablet	Oral use	Blister	20
PT	Produfarma, Lda. (Laboratório Scientia) Estrada de Benfica, 403-B P-1500-077 Lisboa Portugal	Alerdaune	1 mg/ml	Oral Suspension	Oral use	Bottle	100ml
PT	Ratiopharm - Comércio e Indústria de Produtos Farmacêuticos, Lda. Edifício Tejo - 6º Piso Rua Quinta do Pinheiro P-2790-145 Carnaxide Portugal	Loratadina Ratiopharm 10 mg Comprimidos	10 mg	Tablet	Oral use	Blister	7, 10, 14, 20, 28, 20x1, 50, 100, 100x1
PT	Sandoz, GmbH Biochemiestraße 10 A-6250 Kundl Austria	Loratadina Sandoz 10 mg Comprimidos	10 mg	Tablet	Oral use	Blister	7, 10, 14, 20, 21, 30, 50, 60, 100, 100x1, 250

Member State	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical Form	Route of administration	Packaging	Package size
PT	Schering-Plough Farma, Lda. Rua Agualva dos Açores 16 P-2735-557 Agualva- Cacém Portugal	Claritine	10 mg	Tablet	Oral use	Blister	20
PT	Schering-Plough Farma, Lda. Rua Agualva dos Açores 16 P-2735-557 Agualva- Cacém Portugal	Claritine	10 mg	Effervescent tablet	Oral use	Blister	10, 20
PT	Schering-Plough Farma, Lda. Rua Agualva dos Açores 16 P-2735-557 Agualva- Cacém Portugal	Claritine	1 mg/ml	Syrup	Oral use	Bottle	100, 200ml
PT	Schering-Plough Farma, Lda. Rua Agualva dos Açores 16 P-2735-557 Agualva- Cacém Portugal	Claritine Zydis	10 mg	Oral lyophilisate	Oral use	Blister	10, 20
PT	Stada Arzneimittel A.G. Stadastrasse 2-18 D-61118 Bad Vilbel Germany	Loratadina Stada 1 mg/ml Xarope	1 mg/ml	Syrup	Oral use	Bottle	50, 60, 100, 120, 150 ml
PT	Stada Arzneimittel A.G. Stadastrasse 2-18 D-61118 Bad Vilbel Germany	Loratadina Stada 10 mg Comprimidos	10 mg	Tablet	Oral use	Blister	1, 5, 7, 10, 14, 15, 20, 21, 30, 50, 60, 90, 100, 250
PT	Tecnimede - Sociedade Técnico-Medicinal, S.A. Rua Prof. Henrique de Barros - Edf. Sagres, 3º A P-2685-338 Prior Velho Portugal	Profenox	10 mg	Tablet	Oral use	Blister	10, 20

Member State	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical Form	Route of administration	Packaging	Package size
PT	Tecnimede - Sociedade Técnico-Medicinal, S.A. Rua Prof. Henrique de Barros - Edf. Sagres, 3º A P-2685-338 Prior Velho Portugal	Profenox	1 mg/ml	Syrup	Oral use	Bottle	100 ml
SP	Bexal Farmaceutica S.A. Ventura Rodriguez 7 5ª Plta, ES-28008 Madrid, Spain	Loratadina Bexal	10 mg	Tablet	Oral use	Blister	20
SP	Combino Pharma Fructuoso Gelabert 6-8 ES-08970 San Juan Despi Barcelona, Spain	Loratadine Combino Pharm	10 mg	Tablet	Oral use	Blister	20
SP	Industrial Farmacéutica Cantabria Carretera Cazoña-Ardazo s/n ES-39011 Santander, Spain	Fadina	10 mg	Tablet	Oral use	Blister	20
SP	Industrial Farmacéutica Cantabria Carretera Cazoña-Ardazo s/n – ES-39011 Santander, Spain	Loratadina UR	10 mg	Tablet	Oral use	Blister	20
SP	Ipsen Pharma S.A. Ctra. Laureà Miró 395 ES-08980 Sant Feliu de Llobregat Barcelona, Spain	Loratadina Lasa	10 mg	Tablet	Oral use	Blister	20

Member State	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical Form	Route of administration	Packaging	Package size
SP	Kern Pharma S.L. Pol. Ind. Colon II Venus 72, ES-08228 Terrassa Barcelona, Spain	Loratadina Kern	10 mg	Tablet	Oral use	Blister	20
SP	Laboratorio Bayvit Av. Frederic Mompou 5 ES-08960 Sant Just Desvern Barcelona, Spain	Loratadina Bayvit	10 mg	Coated tablet	Oral use	Blister	20
SP	Laboratorio Bayvit Av. Frederic Mompou 5. ES-08960 Sant Just Desvern Barcelona, Spain	Loratadina Bayvit	1 mg/ml	Syrup	Oral use	Bottle	120 ml
SP	Laboratorios Cinfa C/ Olaz-Chipi 10 ES-31620 Huarte, Pamplona, Spain	Loratadina Cinfa	10 mg	Coated tablet	Oral use	Blister	20
SP	Laboratorios Davur S.L. C/ Teide, 4 Parque Empresarial “La Marina” ES-28700 San Sebastian de los Reyes Madrid, Spain	Loratadina Davur	10 mg	Tablet	Oral use	Blister	20
SP	Laboratorios Geminis S.A. Gran Via de Les Cortes Catalanes 7674 ES-08013 Barcelona, Spain	Loratadina Geminis	10 mg	Tablet	Oral use	Blister	20

Member State	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical Form	Route of administration	Packaging	Package size
SP	Laboratorios Geminis S.A. Gran Via de Les Cortes Catalanes 7674 ES-08013 Barcelona Spain	Loratadine Genpril	10 mg	Tablet	Oral use	Blister (PVC/AL)	20
SP	Laboratorios Lesvi S.A. C/ Argent, 1 Pol. Ind. Can Pelegri ES-08755 Castellbisbal, Barcelona, Spain	Civeran Flas	10 mg	Oral lyophilisate	Oral use	Blister	30
SP	Laboratorios Normon S.A. Nieremberg 10 ES-28002 Madrid, Spain	Loratadina Normon	10 mg	Tablet	Oral use	Blister	20
SP	Laboratorios Normon S.A. Nieremberg 10 ES-28002 Madrid, Spain	Loratadina Normon	1 mg/ml	Syrup	Oral use	Bottle	120 ml
SP	Laboratorios Rimafar S.L. Poligono Malpica c/C 4 ES-50016 Zaragoza, Spain	Loratadina Rimafar	10 mg	Tablet	Oral use	Blister	20
SP	Laboratorios Vita S.A. Avda Barcelona 69 Sant Joan Despi ES-08970 Barcelona, Spain	Civeran	10 mg	Tablet	Oral use	Blister (PVC/AL)	20
SP	Laboratorios Vita S.A. Avda Barcelona 69 Sant Joan Despi ES-08970 Barcelona, Spain	Civeran	1 mg/ml	Syrup	Oral use	Bottle	120 ml

Member State	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical Form	Route of administration	Packaging	Package size
SP	Laboratorios Vita S.A. Avda Barcelona 69 Sant Joan Despi ES-08970 Barcelona, Spain	Velodan	10 mg	Tablet	Oral use	Blister (PVC/AL)	20
SP	Laboratorios Vita S.A. Avda Barcelona 69 Sant Joan Despi, ES-08970 Barcelona, Spain	Velodan	1 mg/ml	Syrup	Oral use	Bottle	120 ml
SP	Pharmagenus S.A. Paseo de Gracia 55 1ª ES-08007 Barcelona, Spain	Loratadina Pharmagenus	10 mg	Tablet	Oral use	Blister	20
SP	PLIVA Pharma Iberia, S.A. c/Geológicas 72, Pol. Ind., Urtinsa II, ES-28923 Alcorcón, Spain	Loratadine Pliva	10 mg	Tablet	Oral use	Blister	20
SP	Schering-Plough S.A. Km 36 Carret Nacional 1 ES-28750 San Agustin de Guadalix Madrid, Spain	Claritine Flas	10 mg	Oral lyophilisate	Oral use	Blister	30
SP	Schering-Plough S.A. Km 36 Carret Nacional 1 ES-28750 San Agustin de Guadalix Madrid, Spain	Clarityne	10 mg	Tablet	Oral use	Blister	20

Member State	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical Form	Route of administration	Packaging	Package size
SP	Schering-Plough S.A. Km 36 Carret Nacional 1 ES-28750 San Agustin de Guadalix Madrid, Spain	Clarityne	1 mg/ml	Syrup	Oral use	Bottle	120 ml
SP	Schering-Plough S.A. Km 36 Carret Nacional 1 ES-28750 San Agustin de Guadalix Madrid, Spain	Optimin	10 mg	Tablet	Oral use use	Blister	20
SP	Schering-Plough S.A. Km 36 Carret Nacional 1 ES-28750 San Agustin de Guadalix Madrid, Spain	Optimin	1 mg/ml	Syrup	Oral use	Bottle	120 ml
SP	Tamarang S.A. Balmes 84 4º 2ª ES-08008 Barcelona, Spain	Loratadina Tamarang	1 mg/ml	Syrup	Oral use	Bottle	120 ml
SP	Tamarang S.A. Balmes 84, 4º 2ª ES-08008 Barcelona, Spain	Loratadina Tamarang	10 mg	Tablet	Oral use	Blister	20

Member State	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical Form	Route of administration	Packaging	Package size
SP	Universal Farma S.L. Gran Via Carlos III, 98 7ª planta ES-08028 Barcelona, Spain	Loratadina Merk	10 mg	Tablet	Oral use	Blister	20
SP	Vegal Farmacéutica S.L. Tramontana, 44 ES-28223 Pozuelo de Alarcon Madrid, Spain	Loratadina Vegal	1 mg/ ml	Syrup	Oral use	Bottle	120 ml
SW	A/S GEA Farmaceutisk Fabrik Holger Danskes Vej 89 DK-2000 Fredriksberg Denmark	Loratadin GEA	10 mg	Tablet	Oral use	Blister	7, 10, 20, 21, 30, 100
SW	Astra Zeneca AB S-151 85 Södertälje Sweden	Loratadin Astra Zeneca	10 mg	Tablet	Oral use	Blister	5, 7, 10, 14, 20, 30, 40, 100, 105
SW	Generics (UK) Ltd 12 Station Close Potters Bar Herts EN6 1TL United Kingdom	Loratadin NM Pharma	10 mg	Film-coated tablet	Oral use	Blister	5, 7, 10, 14, 15, 20, 21, 30, 50, 100
SW	Pro Medica AB Box 271 90 S-10252 Stockholm, Sweden	Versal	10 mg	Tablet	Oral use	Blister	7, 14

Member State	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical Form	Route of administration	Packaging	Package size
SW	Sandoz GmbH Biochemiestraße 10 A-6250 Kundl Austria	Loratadin Biochemie	10 mg	Tablet	Oral use	Blister Bottle	7, 10, 14, 20, 21, 30, 50, 60, 100, 250 7, 10, 14, 20, 21, 30, 50, 60, 100, 250
SW	Schering-Plough Europe Rue de Stalle 73 B-1180 Brussels, Belgium	Clarityn	10 mg	Tablet	Oral use	Blister	10, 14, 28, 30 and 100
SW	Schering-Plough Europe Rue de Stalle 73 B-1180 Brussels, Belgium	Clarityn	1mg/ml	Oral solution	Oral use	Bottle	120 ml
SW	Schering-Plough Europe Rue de Stalle 73 B-1180 Brussels, Belgium	Clarityn	10 mg	Effervescent tablet	Oral use	Tube	10, 100
SW	Schering-Plough Europe Rue de Stalle 73 B-1180 Brussels, Belgium	Clarityn-S	10 mg	Oral lyophilisate	Oral use	Blister	12, 30, 100
SW	Stada Arzneimittel AG Stadastraße 2-18 D-61118 Bad Vibel Germany	Loratadin Stada	10 mg	Tablet	Oral use	Blister	1, 5, 7, 10, 14, 15, 20, 21, 30, 50, 60, 90, 100, 250

Member State	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical Form	Route of administration	Packaging	Package size
SW	Stada Arzneimittel AG Stadastraße 2-18 D-61118 Bad Vibel Germany	Loratadin Stada	1 mg/ml	Syrup	Oral use	Bottle (glass)	50, 60, 100, 120, 150 ml
UK	Alpharma Limited Whiddon Valley Barnstaple EX32 8NS UK	Alpharma Loratadine Tablets	10 mg	Tablet	Oral use	Blister Strip	7, 10, 14, 15, 20, 28, 30, 50, 56, 60, 100, 500
UK	Alpharma Limited Whiddon Valley Barnstaple EX32 8NS, UK	Loratadine 5mg/5ml Syrup	1mg/ml	Oral solution	Oral use	Bottle	50, 70, 100, 125, 150, 500ml
UK	Approved Prescription Services Ltd 41 Brampton Road Hampden Park, Eastbourne East Sussex, BN22 9AG, UK	Loratadine 10 mg Tablets	10 mg	Tablet	Oral use	Blister	5, 7, 10, 15, 20, 28, 30, 50, 100
UK	Approved Prescription Services Ltd 41 Brampton Road Hampden Park, Eastbourne East Sussex, BN22 9AG, UK	Loratadine 1mg/1ml Oral Solution	1 mg/ml	Syrup	Oral use	Bottle	50, 60, 100, 120, 150, 200ml
UK	Egis Pharmaceuticals UK Limited 127 Shirland Road London W9 2EP, UK	Loratadine 10 mg Tablets	10 mg	Tablet	Oral use	Blister	30

Member State	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical Form	Route of administration	Packaging	Package size
UK	Generics (UK) Limited Station Close Potters Bar EN6 1TL UK	Loratadine 10 mg film-coated Tablets	10 mg	Film-coated Tablets	Oral use	Blister	5, 7, 10, 14, 15, 20, 21, 30, 50, 100
UK	Lagap Pharmaceuticals Limited Unit 37, Woolmer Way Bordon, Hampshire, GU35 9QE, UK	Loratadine 10 mg tablets	10 mg	Tablet	Oral use	Blister	7, 10, 30
UK	Medis Danmark A/S Havelse Mølle 14 DK-3600 Frederikssund Denmark	Loratadine 10 mg tablets	10 mg	Tablet	Oral use	Blister	7, 10, 14, 20, 30, 50, 100
UK	Niche Generics Limitd Waterford Road Clonmel Co. Tipperary, Ireland	Bioglan Generics Loratadin Tablets	10 mg	Tablet	Oral use	Blister	7, 10, 14, 28, 30, 50, 56, 60, 84, 90, 100, 125, 150
UK	Norton Healthcare Limited Ivax Quays, Albert Basin Armada Way, Royal Docks London, E16 2QJ UK	Hay-Rite Allergy Tablets	10 mg	Tablet	Oral use	Blister	7
UK	Norton Healthcare Limited Ivax Quays, Albert Basin Armada Way, Royal Docks London, E16 2QJ UK	Hayrite Tablets	10 mg	Tablet	Oral use	Blister	20, 30

Member State	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical Form	Route of administration	Packaging	Package size
UK	Ranbaxy UK Ltd 97-107 Uxbridge Road Ealing London UK	Loratadine 10 mg Tablets	10 mg	Tablet	Oral use	Blister Strip	7, 30
UK	Ranbaxy UK Ltd 97-107 Uxbridge Road Ealing London UK	Loratadine 10 mg Tablets	10 mg	Tablet	Oral use	Blister Strip	7, 10, 14, 21
UK	Rockspring Healthcare Ltd Nerin House 26 Bridgeway Street Douglas IM1 1EL – Isle of Man UK	Loratadine 10 mg tablets	10 mg	Tablet	Oral use	Blister	7, 10, 14, 28, 30, 56, 60, 84, 90, 100, 120, 150
UK	Rockspring Healthcare Ltd Nerin House 26 Bridgeway Street Douglas IM1 1EL – Isle of Man UK	Loratadine 10 mg tablets	10 mg	Tablet	Oral use	Blister	7
UK	Schering Plough Ltd Shire Park Welwyn Garden City AL7 1TW UK	Clarityn Rapide Tablets	10 mg	Tablet	Oral use	Blister	1, 7, 8, 10, 30
UK	Schering Plough Ltd Shire Park Welwyn Garden City AL7 1TW UK	Clarityn Syrup	1 mg/ml	Oral solution	Oral use	Bottle	50, 60, 100, 200 ml

Member State	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical Form	Route of administration	Packaging	Package size
UK	Schering Plough Ltd Shire Park Welwyn Garden City AL7 1TW UK	Clarityn Tablets	10 mg	Tablet	Oral use	Blister	2, 5, 7, 10, 14, 20, 21, 30
UK	Sterwin Medicines Limited One Onslow Street Guilford Surrey GU1 4YW UK	Loratadine 10 mg Tablets	10 mg	Tablet	Oral use	Blister	7, 10, 14, 28, 30, 56, 60, 84, 90, 100, 120, 150
UK	Sterwin Medicines Limited One Onslow Street Guilford Surrey GU1 4YW UK	Allergy and Hayfever Relief tablets	10 mg	Tablet	Oral use	Blister	7
UK	Sterwin Medicines Limited One Onslow Street Guilford Surrey GU1 4YW UK	Loratadine 10 mg Tablets	10 mg	Tablet	Oral use	Blister	7, 20, 30, 50, 100
UK	Teva Pharma BV 3640 AE Mijdrecht Netherlands	Teva Loratadine Tablets	10 mg	Tablet	Oral use	Blister	5, 7, 10, 15, 20, 28, 30, 50, 100
UK	Teva Pharma BV 3640 AE Mijdrecht Netherlands	Teva Pharma Loratadine Syrup	1 mg/ml	Syrup	Oral use	Bottle	50, 60, 100, 120, 150, 200 ml
UK	Ranbaxy UK Ltd 97-107 Uxbridge Road Ealing London UK	Loratadine 10 mg Tablets	10 mg	Tablet	Oral use	Blister Strip	7, 30

Member State	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical Form	Route of administration	Packaging	Package size
UK	Ranbaxy UK Ltd 97-107 Uxbridge Road Ealing London UK	Loratadine 10 mg Tablets	10 mg	Tablet	Oral use	Blister Strip	7, 10, 14, 21
UK	Waymade Plc Miles Gray Road Basildon SS14 3FR UK	Waymade Loratadine Tablets	10 mg	Tablet	Oral use	Blister	30

ANNEX II

SCIENTIFIC CONCLUSIONS AND GROUNDS FOR AMENDMENT OF THE SUMMARIES OF PRODUCT CHARACTERISTICS PRESENTED BY THE EMEA

SCIENTIFIC CONCLUSIONS

OVERALL SUMMARY OF THE SCIENTIFIC EVALUATION OF LORATADINE CONTAINING MEDICINAL PRODUCTS (see Annex I)

Loratadine is an anti-histamine compound belonging to the H-1 antagonist group and has been on the market of many Member States for at least 10 years.
In early 1999, the Medical Products Agency (MPA) was made aware of data from the Swedish Medical Birth Registry (SMBR), which indicated that use of loratadine in the first trimester of pregnancy might be associated with an increased risk of hypospadias in the male newborn. The database consisted of 1,020 infants born to women who reported use of loratadine before the first antenatal visit. Further assessment from a preclinical point of view and of the clinical cases resulted in the conclusion that this may have been a random finding. Furthermore, data from a preclinical study did not indicate that loratadine has an anti-androgenic effect, which could be one possible mechanism.
In an analysis from November 2001, the previous signal appeared reinforced. Among 2,780 exposed pregnancies there were in total 15 cases of hypospadias vs. the expected incidence of 6-7 cases. Based on these data, the MPA considered that it could not be excluded that the use of loratadine during the first trimester of pregnancy may be associated with an increased risk of hypospadia.
On 25 April 2002, Sweden triggered a referral to the EMEA under Article 31 of Directive 2001/83/EC, as amended. Based on the data from the Swedish Medical Birth Registry, which could not exclude that the use of loratadine during the first trimester of pregnancy may be associated with increased risk of hypospadia, Sweden considered that there was Community interest in reassessing the full benefit/risk profile of loratadine and requested the CPMP to give an opinion on whether the applications and marketing authorisations for loratadine containing medicinal products should be granted, maintained, changed, suspended or withdrawn.

EFFICACY

A discussion on the efficacy of loratadine containing medicinal products took place in CPMP based on the Rapporteur and Co-Rapporteur's Assessment Reports and the data presented by the Applicants/MAHs.
The CPMP considered that loratadine has been shown to significantly reduce the symptoms of allergic rhinitis (AR), including seasonal allergic rhinitis (SAR) and perennial allergic rhinitis (PAR), and chronic idiopathic urticaria (CIU). For each of these indications, superiority to placebo was demonstrated in the change from baseline of total symptom scores (e.g rhinitis symptom score) or disease symptoms and signs (e.g. skin itching, erythema, hives). Loratadine was also shown to be as effective as comparator antihistamines. The CPMP considered the indication "allergic dermatitis such as chronic urticaria" to be too broad and requested the Applicants/MAHs to provide data in support of indications other than CIU. Following the CPMP's request for data in support of indications other than CIU the Applicants/MAHs restricted the indication to CIU in their proposed SPC submitted as part of their answers.
The CPMP requested the data supporting the indication CIU for children between the age of 2 and 12 years. Based on the responses the CPMP considered that although there are no placebo-controlled data, CIU in children between 2 and 12 years is not a different disease entity compared to the disease in adults and that data from adults can be extrapolated to children, as the pharmaco-kinetic data are supportive.
The CPMP also requested the data supporting the use of loratadine in children below the age of 2 years. Following the CPMP's request for data supporting the use of loratadine below the age of 2 years the Applicants/MAHs restricted the use to children above 2 years of age and the following statement was included in section 4.2: "Efficacy and safety in children under 2 years of age have not been established".
On the basis of the available data the CPMP concluded that loratadine is effective in the relief of symptoms associated with allergic rhinitis and chronic idiopathic urticaria.

SAFETY

The overall safety profile of loratadine containing medicinal products was reviewed by the CPMP. A discussion on the safety of loratadine containing medicinal products took place in CPMP based on the Rapporteur and Co-Rapporteur's Assessment Reports and the data presented by the Applicants/MAHs. The main safety issue discussed was the possible increased risk of hypospadia following the use of loratadine during pregnancy.

General safety

The CPMP reviewed the available data, which included overall summaries of clinical studies and post-marketing data.

The most frequent adverse reactions reported in excess of placebo were somnolence, headache, increased appetite and insomnia. Other adverse reactions reported very rarely during the post-marketing period were: anaphylaxis, dizziness, tachycardia, palpitation, nausea, dry mouth, gastritis, abnormal hepatic function, rash, alopecia, and fatigue.

The CPMP concluded that no additional safety concerns were identified.

Hypospadias

Studies Conducted to Date

Swedish Medical Birth Registry (SMBR)

In Sweden, drug use is recorded at the first antenatal care visit, which for at least 90% of pregnant women is made before week 14 of pregnancy. The recorded drug use in the first trimester is entered into the SMBR, and these data are thereafter linked to data on pregnancy outcome. Thus, drug use is recorded prospectively to pregnancy outcome. Nearly all deliveries (at least 98%) in Sweden are reported to the SMBR, i.e. about 90 000 / year, and the database contains more than 500 000 pregnancies.

In an analysis of data from the SMBR in November 2001, 15 cases of hypospadias were identified among 2,780 loratadine-exposed pregnancies. The total prevalence of hypospadias observed in the SMBR is 2.1 out of 1000 pregnancies (boys and girls). The corresponding figure in children (boys and girls) born by mothers who claim to have taken loratadine during early pregnancy was 5.4. The overall adjusted odds ratio, stratifying for year of birth, maternal age and parity, was 2.3 [95% CI 1.4-3.6]. Among the 15 cases, the severity was recorded as mild in 11 cases, moderate in one case and not recorded in 3 cases.

Hypospadias is a relatively common malformation. Reported background incidences show large variation; however, the CPMP found that the total prevalence of hypospadias in the SMBR falls within the reported background incidences of 0.5 to 3 per 1000 live births.

The CPMP considered that possible biases that have been identified in the SMBR, including misclassifications, would bias the risk estimate towards 1 or not affect it. The existence of misclassifications should be viewed as contributing to the strength of the signal. That the effect of non-differential misclassification bias is to underestimate the real association is in line with known epidemiological theory and experience. That there would be any bias in the opposite direction e.g. through the recording of the drug use (the outcome of the pregnancy is not known at the time of the antenatal visit) or the diagnosis of hypospadias is unlikely. The CPMP found that the known confounding factors have been corrected for in the analyses (e.g. parity, smoking, age etc).

Other birth registries, databases, and Case Control Studies

Data were presented from two other birth registries. When combined they provide experience in 318 loratadine-exposed women during the first trimester of pregnancy. Examination revealed no reports of hypospadias associated with maternal loratadine use and no evidence of an increased rate of major congenital abnormalities among offspring of mothers exposed to loratadine during the first trimester.

The CPMP considered that the presented registry data tend to confirm that loratadine does not represent a major teratogenic risk. However, even if no association between loratadine and hypospadia was identified, it can not be concluded that loratadine does not increase the rate of hypospadias since the number of pregnancies in the registries was too small.

Outcome of pregnancies in women taking loratadine

The CPMP considered the spontaneous post-marketing reports of loratadine use during pregnancy. Approximately 250 cases of loratadine use during pregnancy have been reported. These reports

include the 15 hypospadias cases from the SMBR, and 8 spontaneous reports that were received following the initiation of the Article 31 referral procedure. Based on these reports and taking the estimated worldwide use of loratadine into account, the CPMP concluded that the spontaneous reporting data did not raise concerns regarding the use of loratadine during pregnancy. On the other hand, considering an expected considerable underreporting, these data are not robust enough to conclude that use of loratadine during pregnancy is safe.

The total number of loratadine-exposed pregnancies worldwide is unknown, but is probably large. If spontaneous reporting would provide reliable data, a number of hypospadias would have been expected based on the 'natural' background incidence. Hence, the data presented show that hypospadias have not been spontaneously reported as an adverse drug reaction. Thus, the spontaneous reporting provides minor reassurance regarding the safety of loratadine use in pregnancy.

The information available in the medical literature does not indicate an increased risk of congenital malformation with loratadine use. Neither reports of hypospadias nor reports of congenital malformations associated with loratadine were identified in a search of the published literature. Three studies comparing the outcomes of loratadine-exposed pregnancies to controls were identified. In general, the numbers of loratadine-exposed subjects were small (47 to 93 subjects), the study designs varied (prospective vs. retrospective), and the study details were limited.

The CPMP concluded that the three cited studies do not indicate an increased risk of congenital malformations with loratadine use. However, the total number of women exposed to loratadine in these studies is less than 200.

Preclinical studies

External Male Genitalia Development and Importance of Androgens

The CPMP concluded that antiandrogenic activity is the only currently known non-genetic mechanism for induction of hypospadias. Nevertheless, there are examples where an association between hypospadias and drug intake have been demonstrated in humans e.g. insulins and valproic acid. In these cases, possible mechanisms have not been established, but they are probably not directly related to antiandrogenic activity.

Moreover, the CPMP considered that there is no evidence from the literature or other sources supporting that hypospadias induced via the known mechanism may occur without signs of other hormonally related effects i.e. signs of antiandrogenic actions.

Antiandrogenic endpoints in loratadine studies

The CPMP assessed a number of parameters addressing antiandrogenic potential, including hypospadias in the loratadine reproductive toxicity studies. One of these studies was designed specifically to evaluate the potential antiandrogenic effect of loratadine in male rat offspring. The CPMP considered that the results of this study demonstrated that loratadine did not affect the development of the male F_1 genital tract, including hypospadias, in rats exposed throughout organogenesis and early postnatal development (up to day 4 post partum). The CPMP concluded that there was no indication of antiandrogenic effects in the studied endpoints.

OVERALL CONCLUSION ON BENEFIT/RISK

The CPMP concluded that, the available data for loratadine does not indicate that the compound has either genotoxic or antiandrogenic potential.
The CPMP concluded that the SMBR provides a robust signal that loratadine exposure during pregnancy increases the risk of hypospadia. Reasonable biases that have been identified in the SMBR, including misclassifications, cannot explain the occurrence of the signal. The preclinical data argue against a true drug effect. Thus, based on the available data, a causal relationship can neither be confirmed nor excluded. As a precautionary measure the CPMP recommended, that the appropriate warning in the SPC regarding pregnancy and lactation should be amended to state that use of loratadine during pregnancy is not recommended.
The CPMP concluded that the signal should be further investigated.
The CPMP concluded that loratadine has been shown to be effective in relieving the symptoms associated with Allergic Rhinitis and Chronic Idiopathic Urticaria.
Therefore the CPMP considered that the benefit/risk balance of loratadine containing medicinal products is favourable for the indication "relief of symptoms associated with Allergic Rhinitis and Chronic Idiopathic Urticaria" and recommended the maintenance or the granting of the Marketing Authorisations according to the Summary of Product Characteristics as set out in Annex III of the CPMP Opinion with emphasis to the following:

Section 4.6. Pregnancy and lactation

"*Loratadine was not teratogenic in animal studies. The safe use of loratadine during pregnancy has not been established. The use of {INVENTED NAME} during pregnancy is therefore not recommended."*

GROUNDS FOR AMENDMENT OF THE SUMMARIES OF PRODUCT CHARACTERISTICS

Whereas

- The Committee considered the referral made under article 31 of Directive 2001/83/EC, as amended, for loratadine containing medicinal products;
- The Committee concluded that the SMBR provides a robust signal that loratadine exposure during pregnancy increases the risk of hypospadia. Based on the available data, a causal relationship can neither be confirmed nor excluded. As a precautionary measure the CPMP recommended, that the SPC for loratadine containing medicinal products should be amended to state that the use of loratadine during pregnancy is not recommended;
- The Committee concluded that the signal should be further investigated;
- The Committe considered that loratadine containing medicinal products are effective in the relief of symptoms associated with allergic rhinitis and chronic idiopathic urticaria;
- The Committee, as a consequence considered the benefit/risk balance of loratadine containing medicinal products to be favourable in the relief of symptoms associated with Allergic Rhinitis and Chronic Urticaria.

As a consequence, the CPMP recommended the granting or maintenance of the Applications/Marketing Authorisations for loratadine containing medicinal products referred in Annex I as amended in accordance with the SPC set out in Annex III.

ANNEX III

SUMMARY OF PRODUCT CHARACTERISTICS

Note: This SPC is the one that was annexed to the Commission Decision on this Article 31 referral for loratadine containing medicinal products. The text was valid at that time.

After the Commission Decision, the Member State competent authorities will update the product information as required. Therefore, this SPC may not necessarily represent the current text.

1. NAME OF THE MEDICINAL PRODUCT

{*INVENTED NAME*} {Strength} {Pharmaceutical form}

[See Annex I - To be completed nationally]

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

<Each <tablet><coated tablet><film-coated tablet><effervescent tablet><soluble tablet><oral lyophilisate><oral dispersible tablet> contains 10 mg loratadine>
<Each ml of <syrup><oral solution><oral suspension> contains 1 mg loratadine>

[See Annex I - To be completed nationally]

For excipients, see 6.1.

3. PHARMACEUTICAL FORM

<Tablet> <Coated tablet> <Film-coated tablet>
<Effervescent tablet> <Soluble tablet>
<Oral lyophilisate> <oral dispersible tablet>
<Syrup> <Oral solution> <oral suspension>

<Visual description of the appearance of the product>

[See Annex I - To be completed nationally]

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

{INVENTED NAME} is indicated for the symptomatic treatment of allergic rhinitis and chronic idiopathic urticaria.

4.2 Posology and method of administration

Adults and children over 12 years of age: 10 mg once daily (<one <tablet> <coated tablet> <film-coated tablet><effervescent tablet><soluble tablet> <oral lyophilisate> <oral dispersible tablet>><10 ml (10 mg) of the <syrup><oral solution> <oral suspension>> once daily). The {pharmaceutical form} may be taken without regard to mealtime.

Children 2 to 12 years of age with:
Body weight more than 30 kg: 10 mg once daily (<one <tablet> <coated tablet> <film-coated tablet><effervescent tablet><soluble tablet> <oral lyophilisate> <oral dispersible tablet>><10 ml (10 mg) of the <syrup> <oral solution> <oral suspension>> once daily).

<Body weight 30 kg or less: 5 ml (5 mg) of the <syrup><oral solution> <oral suspension> once daily.>
<The 10 mg strength <tablet><coated tablet> <film-coated tablet> <effervescent tablet> <soluble tablet><oral lyophilisate> <oral dispersible tablet> is not appropriate in children with a body weight less than 30 kg.>

[To be completed nationally]

Efficacy and safety of *{INVENTED NAME}* in children under 2 years of age has not been established.

Patients with severe liver impairment should be administered a lower initial dose because they may have reduced clearance of loratadine. An initial dose of 10 mg every other day is recommended for adults and children weighing more than 30 kg<, and for children weighing 30 kg or less, 5 ml (5 mg) every other day is recommended>.
No dosage adjustments are required in the elderly or in patients with renal insufficiency.

4.3 Contraindications

{INVENTED NAME} is contraindicated in patients who are hypersensitive to the active substance or to any of the excipients in these formulations.

4.4 Special warnings and special precautions for use

{INVENTED NAME} should be administered with caution in patients with severe liver impairment (see 4.2).

<*{INVENTED NAME}* <syrup><oral solution><oral suspension> contains … g of sucrose per … ml. This should be taken into account in patients with diabetes mellitus.>

<Any other warnings necessary for excipients or residues from the manufacturing process>
[To be completed nationally]

The administration of *{INVENTED NAME}* should be discontinued at least 48 hours before skin tests since antihistamines may prevent or reduce otherwise positive reactions to dermal reactivity index.

4.5 Interaction with other medicinal products and other forms of interaction

When administered concomitantly with alcohol, *{INVENTED NAME}* has no potentiating effects as measured by psychomotor performance studies.

Due to the wide therapeutic index of loratadine no clinically relevant interactions are expected and none were observed in the conducted clinical trials (see 5.2).

4.6 Pregnancy and lactation

Loratadine was not teratogenic in animal studies. The safe use of loratadine during pregnancy has not been established. The use of *{INVENTED NAME}* during pregnancy is therefore not recommended.

Loratadine is excreted in breast milk, therefore the use of loratadine is not recommended in breast-feeding women.

4.7 Effects on ability to drive and use machines

In clinical trials that assessed driving ability, no impairment occurred in patients receiving loratadine. However, patients should be informed that very rarely some people experience drowsiness, which may affect their ability to drive or use machines.

4.8 Undesirable effects

In clinical trials in a paediatric population children aged 2 through 12 years, common adverse reactions reported in excess of placebo were headache (2.7%), nervousness (2.3%), and fatigue (1%).

In clinical trials involving adults and adolescents in a range of indications including AR and CIU, at the recommended dose of 10 mg daily, adverse reactions with loratadine were reported in 2 % of

patients in excess of those treated with placebo. The most frequent adverse reactions reported in excess of placebo were somnolence (1.2%), headache (0.6%), increased appetite (0.5%) and insomnia (0.1%). Other adverse reactions reported very rarely during the post-marketing period are listed in the following table.

Immune disorders	Anaphylaxis
Nervous system disorders	Dizziness
Cardiac disorders	Tachycardia, palpitation
Gastrointestinal disorders	Nausea, dry mouth, gastritis
Hepato-biliary disorders	Abnormal hepatic function
Skin and subcutaneous tissue disorders	Rash, alopecia
General disorders and administration site conditions	Fatigue

4.9 Overdose

Overdosage with loratadine increased the occurrence of anticholinergic symptoms. Somnolence, tachycardia, and headache have been reported with overdoses.

In the event of overdose, general symptomatic and supportive measures are to be instituted and maintained for as long as necessary. Administration of activated charcoal as a slurry with water may be attempted. Gastric lavage may be considered. Loratadine is not removed by haemodialysis and it is not known if loratadine is removed by peritoneal dialysis. Medical monitoring of the patient is to be continued after emergency treatment.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: antihistamines – H_1 antagonist, ATC code: R06A X13.
Loratadine, the active ingredient in *{INVENTED NAME}*, is a tricyclic antihistamine with selective, peripheral H_1-receptor activity.

Loratadine has no clinically significant sedative or anticholinergic properties in the majority of the population and when used at the recommended dosage.

During long-term treatment there were no clinically significant changes in vital signs, laboratory test values, physical examinations or electrocardiograms.

Loratadine has no significant H_2-receptor activity. It does not inhibit norepinephrine uptake and has practically no influence on cardiovascular function or on intrinsic cardiac pacemaker activity.

5.2 Pharmacokinetic properties

After oral administration, loratadine is rapidly and well absorbed and undergoes an extensive first pass metabolism, mainly by CYP3A4 and CYP2D6. The major metabolite-desloratadine (DL)- is pharmacologically active and responsible for a large part of the clinical effect. Loratadine and DL achieve

maximum plasma concentrations (T_{max}) between 1–1.5 hours and 1.5–3.7 hours after administration, respectively.

Increase in plasma concentrations of loratadine has been reported after concomitant use with ketoconazole, erythromycin, and cimetidine in controlled trials, but without clinically significant changes (including electrocardiographic).

Loratadine is highly bound (97 % to 99 %) and its active metabolite moderately bound (73 % to 76 %) to plasma proteins.

In healthy subjects, plasma distribution half-lives of loratadine and its active metabolite are approximately 1 and 2 hours, respectively. The mean elimination half-lives in healthy adult subjects were 8.4 hours (range = 3 to 20 hours) for loratadine and 28 hours (range = 8.8 to 92 hours) for the major active metabolite.

Approximately 40 % of the dose is excreted in the urine and 42 % in the faeces over a 10 day period and mainly in the form of conjugated metabolites. Approximately 27 % of the dose is eliminated in the urine during the first 24 hours. Less than 1 % of the active substance is excreted unchanged in active form, as loratadine or DL.

The bioavailability parameters of loratadine and of the active metabolite are dose proportional.

The pharmacokinetic profile of loratadine and its metabolites is comparable in healthy adult volunteers and in healthy geriatric volunteers.

Concomitant ingestion of food can delay slightly the absorption of loratadine but without influencing the clinical effect.

In patients with chronic renal impairment, both the AUC and peak plasma levels (C_{max}) increased for loratadine and its metabolite as compared to the AUCs and peak plasma levels (C_{max}) of patients with normal renal function. The mean elimination half-lives of loratadine and its metabolite were not significantly different from that observed in normal subjects. Haemodialysis does not have an effect on the pharmacokinetics of loratadine or its active metabolite in subjects with chronic renal impairment.

In patients with chronic alcoholic liver disease, the AUC and peak plasma levels (C_{max}) of loratadine were double while the pharmacokinetic profile of the active metabolite was not significantly changed from that in patients with normal liver function. The elimination half-lives for loratadine and its metabolite were 24 hours and 37 hours, respectively, and increased with increasing severity of liver disease.

Loratadine and its active metabolite are excreted in the breast milk of lactating women.

5.3 Preclinical safety data

Preclinical data reveal no special hazard based on conventional studies of safety, pharmacology, repeated dose toxicity, genotoxicity and carcinogenic potential.

In reproductive toxicity studies, no teratogenic effects were observed. However, prolonged parturition and reduced viability of offspring were observed in rats at plasma levels (AUC) 10 times higher than those achieved with clinical doses.

<No evidence of mucous membrane irritation was observed after daily administration of up to 12 tablets (120 mg) of oral lyophilisates into the hamster cheek pouch for five days.>

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

[To be completed nationally]

6.2 Incompatibilities

[To be completed nationally]

6.3 Shelf life

[To be completed nationally]

6.4 Special precautions for storage

[To be completed nationally]

6.5 Nature and contents of container

[See Annex I - To be completed nationally]

7. MARKETING AUTHORISATION HOLDER

[See Annex I - To be completed nationally]

8. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

[To be completed nationally]

10. DATE OF REVISION OF THE TEXT

[To be completed nationally]