SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Loratadine 10mg Allergy Relief Film-Coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains Loratadine 10mg.

Excipient(s) with known effect:
For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Film-coated tablet

Film-coated white round biconvex tablets scored on one side and marked "LR 10" on the other side.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Loratadine tablets are indicated in the treatment of seasonal and perennial rhinitis for the relief of nasal symptoms such as sneezing, itching and discharge; and ocular symptoms such as itching and burning.

Loratadine tablets are also indicated for the relief of itching, reddening and wealing of the skin - symptoms associated with idiopathic chronic urticaria.

4.2 Posology and method of administration

Posology
Adults and children over 12 years of age:
10mg once daily (one film-coated tablet once daily). The film-coated tablet may be taken without regard to mealtime.

Paediatric population

Children 2 to 12 years of age are dosed by weight:
Body weight more than 30 kg: 10 mg once daily (one film-coated tablet once daily).

Bodyweight more than 30kg: 10mg once daily (one tablet once daily).

Bodyweight 30 kg or less: The 10mg strength tablet is not appropriate in children with a body weight less than 30kg. There are other formulations more suitable for children 2 to 12 years old with body weight 30 kg or less.

Safety and efficacy of loratadine in children under 2 years of age has not been established. No data are available.

Patients with hepatic impairment
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.

Patients with renal impairment
No dosage adjustments are required in the elderly or in patients with renal insufficiency.

Elderly
No dosage adjustments are required in the elderly

Method of administration
Loratadine tablets are for oral use.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Loratadine should be administered with caution in patients with severe liver impairment (see section 4.2).

Caution is required with concomitant use of drugs which affect hepatic cytochromes P450 3A4 and 2D6. (see section 4.5; interaction with other medicinal products and other forms of interaction).

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

Loratadine may cause dry mouth in certain patients. Therefore during long-term treatment, good oral hygiene is important for these patients, because dry mouth may increase the risk of caries.

This medicinal product contains lactose; thus patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

When administered concomitantly with alcohol, loratadine has no potentiating effects as measured by psychomotor performance studies.

Potential interaction may occur with all known inhibitors of CYP3A4 or CYP2D6 resulting in elevated levels of loratadine (see Section 5.2), which may cause an increase in adverse events.

Loratadine is metabolised in the liver by CYP2D6, but also and most preferentially by CYP3A4.

Cimetidine inhibits both of these cytochromes; erythromycin and ketoconazole both inhibit CYP3A4, whilst amfebutamone/ bupropion inhibits CYP2D6. When these drugs are given concomitantly with Loratadine increased plasma levels of loratadine are seen but these have not been associated with adverse effects or changes to electrocardiogram. Patients may need to be initiated at a lower dose if taking amfebutamone/ bupropion concomitantly.

Quinidine, fluconazole and fluoxetine are also known to inhibit these cytochromes.

4.6 Fertility, Pregnancy and lactation

Pregnancy
A large amount of data on pregnant women (more than 1000 exposed outcomes) indicate no malformative nor feto/ neonatal toxicity of loratadine. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity (See section 5.3). As a precautionary measure, it is preferable to avoid the use of loratadine during pregnancy.
Breast-feeding
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.

Adverse events are listed below by system organ class and frequency. Frequencies are defined as: very common (≥1/l0), common (≥1/100 and <1/10), uncommon (≥1/1000 and <1/100), rare (≥ 1/10,000 and <1/1000) and very rare (<1/10,000).

	Common (≥ 1/100 to <1/10)	Uncommon (≥ 1/1,000 to <1/100)	Very Rare (< 1/10,000)
Immune system disorders			Hypersensitivity reactions (including angioedema and anaphylaxis)
Metabolism and nutrition disorders		Increased appetite	
Nervous system disorders	Headache, somnolence, nervousness	Insomnia	Dizziness, convulsions
Cardiac disorders			Tachycardia, palpitation.
Respiratory, thoracic and mediastinal disorders			
Gastrointestinal disorders			Nausea, , dry mouth and gastritis
Hepatobiliary disorders			Abnormal hepatic functions
Skin and subcutaneous tissue disorders			Rash, alopecia
General disorders and administration site conditions			Fatigue

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

4.9 Overdose

Overdose with loratadine increases 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 for patients. 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 for systemic use.
ATC code: RO6A X13

Loratadine is an antihistamine with a tricyclic structure and has a selective and antagonistic activity on peripheric H1-receptors. It is long acting and rapidly effective with no sedative or anticholinergic activity in the majority of the population and when used at the recommended dosage.

In CNS-activity studies loratadine 10 mg did not show depressive or acute anticholinergic activity.

Loratadine does not readily cross the blood brain barrier and shows a very low affinity for brain receptors.

During prolonged treatment no clinically relevant changes were observed in vital functions, laboratory parameters, physical examination or electrocardiograms. In studies with dosages of loratadine tablets 2 to 4 times higher than the recommended dose of 10 mg, a dose-related increase in the incidence of somnolence was observed.

Loratadine has no significant affinity for histamine H2-receptors, does not inhibit the absorption of norepinephrine and exhibits hardly any effect on the cardiovascular function in intrinsic cardiac pacemaker activity. In a study in which loratadine tablets were administered at four times the clinical dosage during a period of 90 days no clinically significant increase in QTc-interval was seen on ECGs.

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 (Tmax) 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 (Cmax) increased for loratadine and its metabolite as compared to the AUCs and peak plasma levels (Cmax) 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 (Cmax) 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 with loratadine reveal no special hazard for humans based on conventional studies of safety, pharmacology, repeated dose toxicity, genotoxicity, teratogenicity and carcinogenicity.

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.

Chronic toxicity studies in rats (between 2 – 240 mg/kg/day for up to 12 months) and monkeys (between 0.4 – 90 mg/kg/day for up to 17 months) demonstrated some anticholinergic effects and dose-related reversible phospholipidosis.

The clinical relevance of the findings of phospholipidosis is uncertain.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core
Lactose monohydrate
Microcrystalline cellulose
Maize starch
Pregelatinized starch
Hydrated colloidal silica
Magnesium stearate

Film coat
Hypromellose
Macrogol 400 and 6000

Polishing agents
Carnauba wax
Talc

6.2 Incompatibilities

None known.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store in the original package.

6.5 Nature and contents of container

PVC/Aluminium blister packs of 7 tablets.

6.6 Special precautions for disposal

None

7 MARKETING AUTHORISATION HOLDER

Cooper Consumer Health B.V.,
Verrijn Stuartweg 60, 1112 AX Diemen,
The Netherlands

8 MARKETING AUTHORISATION NUMBER(S)

PL 60682/0021

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

05/04/2011

10 DATE OF REVISION OF THE TEXT

18/06/2025