SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Loratadine 10 mg Tablets
Lloydspharmacy Allergy Relief 10 mg Tablets
E M Pharma One A Day Hayfever Relief 10 mg Tablets
Careway One-a-day Allergy Relief 10 mg Tablets
essential Waitrose one a day allergy relief 10mg tablets
Teva One-a-Day Allergy Relief 10mg tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 10 mg of loratadine.

Excipient(s) with known effect
Each tablet contains 62.5 mg of lactose.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet

White, oval tablets, scored on one side and plain on the other side, debossed “L” and “10” on each side of the scoreline.

4. CLINICAL PARTICULARS

4.1. Therapeutic Indications

Loratadine is indicated for the symptomatic treatment of allergic rhinitis and chronic idiopathic urticaria in adults and children over the age of 2 years with a body weight more than 30 kg.

4.2. Posology and Method of Administration

Posology
Adults and children over 12 years of age: 10 mg once daily (one tablet once daily).

Paediatric population
Children 2 to 12 years of age are dosed by weight:
Body weight more than 30 kg: 10 mg once daily (one tablet once daily).
The 10 mg strength tablet is not appropriate in children with a body weight less than 30 kg. There are other formulations more suitable for children aged 2 to 12 years old with body weight 30 kg or less.

Efficacy and safety of Loratadine in children under 2 years of age has not been established. No data are available.

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.

Renal impairment
No dosage adjustments are required in patients with renal insufficiency.

Elderly
No dosage adjustments are required in the elderly.

Method of administration
Oral use. The tablet may be taken without regard to mealtime.

4.3. Contraindications

Loratadine is contraindicated in patients who are hypersensitive to loratadine 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).

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.

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.

4.5. Interaction with other Medicaments 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.

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).

Paediatric population
Interaction studies have only been performed in adults.

4.6. Fertility, pregnancy and lactation

Pregnancy

A large amount of data on pregnant women (more than 1000 exposed outcomes) indicates 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.

Fertility
There are no data available on male and female fertility.

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

Summary of safety profile
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.

Within the system organ classes, adverse reactions are listed under headings of frequency (number of patients expected to experience the reaction), using the following categories:

Very Common (≥ 1/10)
Common (≥1/100 to <1/10)
Uncommon (≥1/1,000 to <1/100)
Rare (≥1/10,000 to <1/1,000)
Very rare (<1/10,000)
Not known (cannot be estimated from the available data)

Common (may affect less than 1 in 10 patients)
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%).

Very rare (may affect less than 1 in 10,000 patients)
Other adverse reactions reported very rarely during the post-marketing period are listed in the following table.

Immune system disorders	Hypersensitivity reactions (including angioedema and anaphylaxis)
Nervous system disorders	Dizziness, convulsion
Cardiac disorders	Tachycardia, palpitation
Gastrointestinal disorders	Nausea, dry mouth, gastritis
Hepatobiliary disorders	Abnormal hepatic function
Skin and subcutaneous tissue disorders	Rash, alopecia
General disorders and administration site conditions	Fatigue

Not known (cannot be estimated from the available data)

Investigations	Weight increased

Paediatric population
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%).

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 or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9. Overdose

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

Management
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.

Mechanism of action
Loratadine, the active ingredient in this medicine, is a tricyclic antihistamine with selective peripheral H_1-receptor activity.

Pharmacodynamic effects
Loratadine has no clinically significant sedative of 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.

Human histamine skin wheal studies following a single 10mg dose has shown that the antihistamine effects are seen within 1-3 hours reaching a peak at 8-12 hours and lasting in excess of 24 hours. There was no evidence of tolerance to this effect after 28 days of dosing with loratadine.

Clinical efficacy and safety
Over 10,000 subjects (12 years and older) have been treated with loratadine 10 mg tablets in controlled clinical trials. Loratadine 10 mg tablets once daily was superior to placebo and similar to clemastine in improving the effects on nasal and non-nasal symptoms of AR. In these studies somnolence occurred less frequently with loratadine than with clemastine and about the same frequency as terfenadine and placebo.

Among these subjects (12 years and older), 1000 subjects with CIU were enrolled in placebo controlled studies. A once daily 10mg dose of loratadine was superior to placebo in the management of CIU as demonstrated by the reduction of associated itching, erythema and hives. In these studies the incidence of somnolence with loratadine was similar to placebo. n of associated itching, erythema and hives. In these studies the incidence of somnolence with loratadine was similar to placebo.

Paediatric population
Approximately 200 paediatric subjects (6 to 12 years of age) with seasonal allergic rhinitis received doses of loratadine syrup up to 10mg once daily in controlled clinical trials. In another study, 60 paediatric subjects (2 to 5 years of age) received 5mg of loratadine syrup once daily. No unexpected adverse events were observed.

The paediatric efficacy was similar to the efficacy observed in adults.

5.2. Pharmacokinetic Properties

Absorption
Loratadine is rapidly and well-absorbed. Concomitant ingestion of food can delay slightly the absorption of loratadine but without influencing the clinical effect. The bioavailability parameters of loratadine and of the active metabolite are dose proportional.

Distribution
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.

An increase in the 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).

Biotransformation
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.

Elimination
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 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.

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

Renal impairment
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 those 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.

Hepatic 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.

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

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 administrations 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

Lactose
Maize starch
Pregelatinised starch 1500
Magnesium stearate.

6.2. Incompatibilities

Not applicable

6.3. Shelf Life

3 years

6.4. Special Precautions for Storage

No special storage conditions

6.5. Nature and Contents of Container

The tablets are packed in transparent PVC/PVdC (PVC: 250 µm thick, PVdC coating: 40 g/m^2 or 60 g/m^2) aluminium blisters or white opaque PVC/PVdC (PVC: 250 µm thick, PVdC coating: 40 g/m^2) aluminium blisters containing 5, 7, 10, 14, 15, 20, 28 and 30 tablets. Not all pack sizes may be marketed.

6.6. Special precautions for disposal

No special requirements

7. MARKETING AUTHORISATION HOLDER

Teva UK Limited,
Ridings Point, Whistler Drive,
Castleford, WF10 5HX, United Kingdom

8. MARKETING AUTHORISATION NUMBER

PL 00289/0371

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

08/08/02

10. DATE OF REVISION OF THE TEXT

26/06/2025