# Product Summary

## 1. Trade Name of the Medicinal Product

Loratadine 10 mg Tablets
Loratohist 10 mg Tablets
Lloydspharmacy Non-Drowsy Allergy Relief
Moss Pharmacy Non-Drowsy Allergy Relief
Unichem Non-Drowsy Allergy Relief
Co-op Non-Drowsy Allergy Relief

## 2. Qualitative and Quantitative Composition

Each tablet contains 10 mg of loratadine.
For excipients, see 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.

# Clinical Particulars

## 4.1. Therapeutic Indications

Loratadine Tablets are indicated for the relief of symptoms associated with seasonal and perennial allergic rhinitis, such as sneezing, nasal discharge and itching and ocular itching and burning. Loratadine Tablets are also indicated for the relief of symptoms associated with idiopathic chronic urticaria.

## 4.2. Posology and Method of Administration

*Adults, (including the elderly) and children 12 years of age and over:*
One 10 mg tablet once daily.

## 4.3. Contra-Indications

Loratadine Tablets are contraindicated in patients who have shown hypersensitivity or idiosyncrasy to their components.

## 4.4. Special Warnings and Precautions for Use

None.

## 4.5. Interactions with other Medicaments and other forms of Interaction

When administered concurrently with alcohol, Loratadine Tablets have no potentiating effects as measured by psychomotor performance studies. Loratadine is metabolised by hepatic cytochromes P450 3A4 and 2D6. Concomitant therapy with drugs which inhibit or

are metabolised by either system may therefore elevate plasma concentrations of either drug and adverse reactions might result.

Studies indicate that cimetidine, which inhibits both enzymes, and erythromycin or ketoconazole, which inhibit P450 3A4, each increased loratadine concentrations, although no adverse effects, clinical or electro-cardiographic, were observed. Other drugs known to inhibit either P450 3A4 or P450 2D6 are quinidine, fluconazole or fluoxetine.

### 4.6. Pregnancy and Lactation

Loratadine Tablets should not be administered during pregnancy. There is no experience of the use of loratadine in human pregnancy. In animal studies loratadine was not teratogenic, at high doses some embryotoxic effects were observed. Since loratadine is excreted in breast milk it should not be administered to lactating women.

### 4.7. Effects on Ability to Drive and Use Machines

Loratadine Tablets have no clinically significant sedative effect at recommended dosage.

### 4.8. Undesirable Effects

During controlled clinical studies, the incidence of adverse effects associated with Loratadine 10 mg Tablets treatment was comparable to that associated with placebo. Loratadine Tablets had no clinically significant sedative or anticholinergic properties. Other events, fatigue, nausea and headache, were reported rarely.

Tachycardia and syncope have been reported rarely. Causality has not been established.
Spontaneous adverse events reported rarely include: alopecia, anaphylaxis, abnormal hepatic function and supraventricular tachyarrhythmias.

### 4.9. Overdose

In the event of overdosage, treatment, which should be started immediately, is symptomatic and supportive. The patient should be induced to vomit, even if emesis has occurred spontaneously (ipecacuanha is a preferred method), but not in patients with impaired consciousness.

Administration of activated charcoal as a slurry with water may be attempted following emesis. If vomiting is unsuccessful or contraindicated, gastric lavage should be performed. It is not known whether loratadine is dialysable. After emergency treatment, the patient should continue to be medically monitored.

## Pharmacological Properties

### 5.1. Pharmacodynamic Properties

Loratadine is a cyproheptadine derivative, structurally related to azatadine. It exhibits potent, long acting $H_1$-antihistamine activity with no central sedative or anticholinergic

effects. In man, nasal and other signs and symptoms of allergic rhinitis are relieved rapidly after oral administration.

### 5.2. Pharmacokinetic Properties

Loratadine is well absorbed and is almost totally metabolised. It has a distribution half-life of one hour and an elimination half life of 15.3 hours. Approximately 81% of the $^{14}C$ labelled dose is excreted in the urine (40%) and faeces (41%) over a 10 day period. Approximately 27% of the dose is eliminated in the urine during the first 24 hours. Pharmacokinetics in healthy adult volunteers and healthy geriatric volunteers are comparable. Steady state levels of loratadine are reached after the fifth dose.

### 5.3. Preclinical Safety Data

Loratadine was relatively non toxic when administered orally or intraperitoneally in single doses to mice or rats. Oral $LD_{50}$, values were estimated to be greater than 5000mg/kg in both species. Rising single doses up to 1280mg/kg were relatively well tolerated in monkeys.

In repeated dose studies, rats were treated orally for periods up to 12 months with doses ranging from 2-240mg/kg/day; monkeys were treated for up to 17 months with doses ranging from 0.4-90mg/kg/day.

Anticholinergic effects were observed in both species. Evidence of phospholipidosis was also observed; the incidence and severity was dose related and was more pronounced in the rat. It appeared to be reversible.
No evidence of phospholipidosis was observed in man following treatment with 40mg/kg/day loratadine for 3 months. Studies demonstrate that loratadine is not a carcinogen, mutagen or teratogen.

## 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, 15, 20, 28, 30, 50, 100 tablets.

**6.6. Instruction for Use/Handling**

No special requirements

## Administrative Data

**7. Marketing Authorisation Holder**

TEVA UK Limited
Brampton Road, Hampden Park
Eastbourne, East Sussex, BN22 9AG

**8. Marketing Authorisation Number**

PL 0289/0371

**9. Date of First Authorisation/Renewal of Authorisation**

08/08/02

**10. Date of (Partial) Revision of the Text**
20th March 2010

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