Summary of Product Characteristics

1. NAME OF THE MEDICINAL PRODUCT

LORAZIM - 10 (Loratadine Tablets 10 mg)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each uncoated tablet contains;
Loratadine (Micronized) USP 10 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet

White circular flat beveled edges uncoated tablets, having break line on one side and plain on other side

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Loratadine Tablets 10mg is indicated for the symptomatic treatment of allergic rhinitis and chronic idiopathic urticaria.

4.2 Posology and method of administration

Dosage

Adults: 10 mg once daily or one tablet once daily.

Pediatric population
Children aged 6 years and over: body weight over 30 kg: 10 mg once daily.
Children under 6 years old or weighing 30 kg or less: other more suitable pharmaceutical forms exist. Children under 2 years of age: The efficacy and safety of Loratadine Tablets 10mg have not been established.

Patients with hepatic impairment
In patients with severe hepatic impairment the starting dose should be reduced due to a risk of reduced clearance of loratadine. A starting dose of 10 mg every other day is recommended for adults and children over 30 kg.

Elderly patients or patients with renal insufficiency
No dosage adjustment is necessary in elderly patients or patients with renal insufficiency.

Mode of administration
The tablet can be taken without regard to meals.

4.3 Contraindications

Loratadine Tablets 10mg is contraindicated in case of hypersensitivity to loratadine or to any of the drug's excipients

4.4 Special warnings and precautions for use

Loratadine Tablets 10mg should be used with caution in severe hepatic impairment (see section 4.2).
This medicine contains lactose. Its use is not recommended in patients with galactose

intolerance, Lapp lactase deficiency or glucose or galactose malabsorption syndrome (rare hereditary diseases).

Administration of Loratadine Tablets 10mg should be discontinued at least 48 hours before carrying out skin tests for the diagnosis of allergy because antihistamines may inhibit or reduce the skin response.

4.5 Interaction with other medicinal products and other forms of interaction

Psychomotor performance studies have not shown any potentiation of the effects of Loratadine Tablets 10mg during the simultaneous administration of alcohol.

The risk of interactions with inhibitors of CYP3A4 or CYP2D6 cytochromes resulting in increased plasma concentrations of loratadine may increase the risk of occurrence of adverse reactions (see section 5.2).

4.6 Fertility, pregnancy and lactation

Pregnancy

Animal studies have not revealed any teratogenic effect of loratadine. The safety of loratadine during pregnancy has not been established. Therefore, the use of Loratadine Tablets 10mg during pregnancy is not recommended.

Feeding with milk

Loratadine is excreted in breast milk. Therefore, the administration of loratadine during lactation is not recommended

4.7 Effects on ability to drive and use machines

In clinical studies evaluating the ability to drive vehicles, no harmful effects were observed in patients receiving loratadine. However, patients should be informed that very rarely in some people drowsiness has been described which could affect their ability to drive or use machines.

4.8 Undesirable effects

During clinical studies conducted in the pediatric population, in children aged 2 to 12 years, the common adverse effects reported with a greater frequency than with placebo were: headache (2.7%), nervousness (2.3%) and fatigue (1%).

In clinical studies conducted in adults and adolescents in the indications allergic rhinitis and chronic idiopathic urticaria, at the recommended dose of 10 mg, adverse effects with loratadine were reported in 2% more patients than those treated with placebo. The most frequently reported adverse effects with a greater frequency than with placebo were: somnolence (1.2%), headache (0.6%), increased appetite (0.5%) and insomnia (0.1 %).

The other adverse effects very rarely reported since marketing are listed in the following table:

Immune System Disorders	Hypersensitivity reaction (Including anaphylaxis and angioedema)
Nervous system disorders	Dizziness, convulsions
Heart conditions	Tachycardia, palpitations
Gastrointestinal disorders	Nausea, dry mouth, gastritis
Hepatobiliary disorders	Liver Function disorders
Skin and subcutaneous tissue disorders	Rash, alopecia

General disorders and administration site conditions	Fatigue
Investigations	Weight increase (frequency unknown)

Reporting of suspected adverse reactions
The reporting of suspected adverse reactions after authorization of the medicinal product is important. It allows continuous monitoring of the benefit/ risk ratio of the medicinal product. Health professionals report any suspected adverse effects via website: www.zimlab.in

4.9 Overdose

Loratadine overdose increases the occurrence of anticholinergic symptoms. Drowsiness, tachycardia and headache have been reported with overdoses.
In case of overdose, symptomatic treatment and maintenance of vital functions are recommended. Activated charcoal suspended in water can optionally be administered. Gastric lavage may be considered. Loratadine is not removed by hemodialysis and it is not known whether peritoneal dialysis can remove it. The patient should remain under medical supervision after emergency treatment.

5. Pharmacological Properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antihistamines For Systemic Use, ATC code: R06AX13.
Loratadine, the active ingredient of Loratadine Tablets 10mg, is a tricyclic antihistamine acting selectively on peripheral H1 receptors.
Loratadine does not exert a significant sedative or anticholinergic effect in most of the population when used at the recommended dose.
During long-term treatment, no clinically significant changes in vital functions, biological parameters, clinical examination or electrocardiographic tracings were observed.
Loratadine has no significant action on H2 receptors. It does not inhibit norepinephrine uptake and has virtually no influence on cardiovascular functions or intrinsic pacemaker activity

5.2 Pharmacokinetic properties

Following oral administration, loratadine is rapidly and well absorbed, and undergoes extensive hepatic first-pass metabolism, primarily by CYP3A4 and CYP2D6. The major metabolite - desloratadine - is pharmacologically active and largely responsible for the clinical effect. Maximum plasma concentrations of loratadine and desloratadine are reached (Tmax), respectively, between 1-1.5 hours and 1.5-3.7 hours after administration.

In controlled clinical studies, an increase in plasma concentrations of loratadine has been reported during the simultaneous administration of ketoconazole, erythromycin or cimetidine, but without significant clinical consequences (or changes in ECG tracings). The binding of loratadine to circulating proteins is intense (97% to 99%), whereas that of the metabolite is more moderate (73% to 76%). In healthy volunteers, the distribution half-lives of loratadine and its active metabolite are approximately 1 and 2 hours, respectively. The major elimination half-life in healthy volunteers was 8.4 hours (range 3-20 hours) for loratadine and 28 hours (range 8.8-92 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 as 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 as unchanged active loratadine or desloratadine.

The bioavailability of loratadine and its active metabolite is dose dependent.
The pharmacokinetic profile of loratadine and its metabolites is comparable in healthy adult and elderly volunteers.

Concomitant ingestion of food may cause a slight delay in the absorption of loratadine without affecting the clinical effect.
In patients with chronic renal failure, the AUC and peak plasma concentrations (Cmax) of loratadine and its metabolite were higher than the AUC and peak plasma concentrations (Cmax) observed in patients with impaired function. Normal kidney. The mean elimination half-lives of loratadine and its metabolite were not significantly different from those observed in normal subjects. Hemodialysis has no effect on the pharmacokinetics of loratadine and its active metabolite in patients with chronic renal failure.

In patients with chronic alcoholic liver disease, the observed AUC and peak plasma concentrations (Cmax) of loratadine were doubled while the pharmacokinetic profile of the active metabolite was not significantly altered from that patients with normal hepatic function. The elimination half-lives of loratadine and its metabolite were 24 hours and 37 hours, respectively, and increased with the severity of hepatic injury.

Loratadine and its active metabolite are excreted in breast milk in nursing women.

5.3 Preclinical safety data
Preclinical data reveal no specific hazard for humans based on conventional studies of safety, pharmacology, repeated dose toxicity, genotoxicity or carcinogenicity.

The study of reproductive functions revealed no teratogenic effects in animals. However, prolonged parturitions and reduced offspring viability were observed in rats exposed to plasma levels (AUC) 10 times higher than those achieved with the doses used in the clinic.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Colloidal anhydrous silica
Maize starch
Microcrystalline cellulose
Lactose
Sodium starch Glycolate (Type A)
Magnesium stearate
Purified talc

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
3 years

6.4 Special precautions for storage
Store at a temperature not exceeding 30°C, protect from light and moisture.

6.5 Nature and contents of container
10 x 10 Tablets Alu- Alu Blister Pack

6.6 Special precautions for disposal
No special requirements.

7. MARKETING AUTHORISATION HOLDER
Zim Laboratories Limited.
Sadoday Gyan (Ground Floor),
Opp. NADT, Nelson Square,
Nagpur – 440013
India.

8. MARKETING AUTHORISATION NUMBER(S)
3374/2878/NMR/2016

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24-07-2021

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29/06/2023