Product Information

Summary of Product Characteristics (SmPC)

1. **Name of the medicinal product:**

   LORATADINE CHEWABLE TABLETS USP 10 MG

2. **Qualitative and Quantitative composition:**

   Composition:

   Each chewable tablet contains:

   Loratadine USP ..... 10 mg

   Excipients ..... q.s.

3. **Pharmaceutical Form:**

   Tablets for Oral Administration.

4. **Pharmacological Particulars:**

4.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antihistamines – H1 antagonist,

ATC code: R06AX13

Mechanism of action

Loratadine, the active ingredient in Loratadine Chewable Tablets, is a tricyclic antihistamine with selective, peripheral H1-receptor activity.

Pharmacodynamic effects

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 H2-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 10 mg 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.

4.2 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.

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 (Tmax) 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.

5. Clinical Particulars:

5.1 Therapeutic Indications:

Loratadine Chewable Tablets are 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.

5.2 Posology and method of administration:

Posology

Adults and children over 12 years of age:

10mg once daily (one oral lyophilisate once daily).

Paediatric population

Children 2 to 12 years of age are dosed by weight:

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

Bodyweight 30kg or less: The 10mg strength oral lyophilisate 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 30kg or less.

Safety and efficacy of Loratadine Chewable Tablets Allergy Tablets in children under 2 years of age has not been established.

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 10mg every other day is recommended for adults and children weighing more than 30kg.

Patients with 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 oral lyophilisate may be taken without regard to mealtime. Water or other liquid is not needed to swallow the tablet.

Carefully peel opens an individual blister. Place it in the mouth and it will disperse instantly.

Method of administration

Oral use.

5.3 Contraindications:

Hypersensitivity to the active substance.

5.4 Special warning and precaution for use:

Loratadine Chewable Tablets should be administered with caution in patients with severe liver impairment.

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

5.5 Interaction with other medicinal products and other forms of interaction:

Potential interaction may occur with all known inhibitors of CYP3A4 or CYP2D6 resulting in elevated levels of Loratadine, which may cause an increase in adverse events.

5.6 Pregnancy and Lactation:

Pregnancy

As a precautionary measure, it is preferable to avoid the use of Loratadine Chewable Tablets

Allergy Tablets during pregnancy.

Breast-feeding

Loratadine is excreted in breast milk. Therefore, the use of Loratadine Chewable Tablets is not recommended in breast-feeding women.

Fertility

There are no data available on male and female fertility.

5.7 Effects on the ability to drive and use machines:

None

5.8 Undesirable effects:

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

5.9 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.

5.10 Pre-clinical Safety:

Not Applicable

6. Pharmaceutical Particulars:

6.1 List of Excipients:

- Lactose BP
- Microcrystalline Cellulose BP
- Maize starch BP
- P.V.P.K 30 (Povidone) BP
- Sodium methyl Paraben BP
- Sodium propyl Paraben BP
- Purified Water BP
- Sodium starch glycolate BP
- Colloidal silicon Dioxide BP
- Purified Talc BP
- Magnesium Stearate BP
- Aspartame BP

6.2 Incompatibilities: None

6.3 Shelf Life: 36 months.

6.4 Special Precautions for storage:

Store at below 30°C. Protect from light.

Tablets are to be chewed before swallowing.

Keep out of reach of children.

6.5 Nature and contents of container:

1X10 ALU-ALU blister, such 10 Blisters packed in carton along with pack insert.

6.6 Special precautions for disposal and other handling:

None

7. Marketing Authorization Holder:

Ratnatris Pharmaceuticals Pvt. Ltd.

Survey no. 416, At- Indrad (382715)

Taluka-Kadi, Dist-Mehsana,

Gujarat, India

8. Marketing Authorization Number:

NA

9. Date of first Authorization /renewal of the authorization:

NA

10. Date of revision of text:

NA