SCOTT-EDIL PHARMACIA LTD.

56, E.P.I.P, Phase –I, Jharmajri, Baddi, Distt. Solan-173205 (HP) , India

Summary of Product Characteristics (SPC)

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

Loratadine Dispersible Tablets 10mg

1.1 Strength

10mg.

1.2 Pharmaceutical form

Tablets for Oral Administration.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

2.1 Qualitative declaration

Each uncoateddispersible tablet contains:

Loratadine USP……10 mg

Excipients…….. q.s.

3. PHARMACEUTICAL FORM

Tablets for oral administration.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

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

4.2 Posology and method of administration:

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

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

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

Body weight 30 kg or less: The 10mg strength tablet is not appropriate in children with a body weight less than 30kg.

Efficacy and safety of Loratadine 10 mg Tablets in children under 2 years of age has not been established. The use is therefore not recommended in these patients.

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, and for children weighing 30kg or less, 5mg every other day is recommended.

No dosage adjustments are required in older people or in patients with renal insufficiency.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients

4.4 Special warnings and precautions for use

Loratadine 10 mg Tablets should be administered with caution in patients with severe liver impairment.

The administration of Loratadine 10 mg Tablets should be discontinued at least 48 hours before skin tests since antihistamines may prevent or reduce otherwise positive reactions to dermal reactivity index.

This medicinal product contains lactose monohydrate. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucosegalactose malabsorption should not take this medicine.

4.5 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%).

4.6 Interaction with other medicinal products and other forms of Interaction

There are no significant interactions between loratadine and food.

When administered concomitantly with alcohol, Loratadine 10 mg Tablets 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 , which may cause an increase in adverse events.

Due to the wide therapeutic index of loratadine no clinically relevant interactions are expected and none were observed in the conducted clinical trials .

4.7 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 10mg Tablets during pregnancy.

Breast-feeding

Loratadine is excreted in breast milk, therefore the use of loratadine is not recommended in breast-feeding women

4.8 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.

4.9 Undesirable effects

Summary of the safety profile

In clinical trials involving adults and adolescents in a range of indications including allergic rhinitis (AR) and chronic idiopathic urticaria (CIU), at the recommended dose of 10mg 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%).

4.10 Overdose

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

In the event of overdosage, 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

Pharmacodynamic Properties

Pharmacotherapeutic group: Antihistamine.

ATC code: R06AX13

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 (T_{max}) 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline Cellulose PH102	USP
Aspartame	USP
Neotame	USP
Anhydrous Lactose	USP
Flavour Dry sweet orange Powder	IH
Colloidal Silicon Dioxide	USP
Croscarmellose Sodium	USP
Sodium Starch Glycolate	USP

6.2 Incompatibilities

No incompatibilities have been identified.

6.3 Shelf life

36 Months

6.4 Special precautions for storage

Store at a temperature not exceeding 30°C. Protect from light.

6.5 Nature and contents of container

10 x 10 tablet are packed in a carton along with leaflet.

6.6 Special precautions for disposal and other handling

No Special requirements

7. Manufactured By

Scott-Edil Pharmacia Limited,
56, EPIP, Phase-I, Jharmajri,
Baddi, Distt. Solan- 173205 (H.P)
INDIA

8. Marketed By
First j POCCO PHARM LTD.

9. Date of revision of the text
January 2022

10. DOSIMETRY (IF APPLICABLE)
Not applicable

11. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS (IF APPLICABLE)
Not Applicable