December 2023

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

Loradine (Loratadine 10mg tablet)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 10 mg loratadine.

Excipient(s) with known effects:

Each tablet contains 58.0 mg of lactose monohydrate

For the full list of excipients, see section 6.1.

3. Pharmaceutical form:

Tablet

4. Clinical Particulars:

4.1 Therapeutic indication:

Relief of symptoms associated with allergic rhinitis e.g. sneezing, nasal discharge and itching, as well as ocular itching and burning.

Chronic urticaria and other allergic dermatologic disorders.

4.2 Posology and method of administration:

Adults and children ≥ 12 years: 1 tablet daily.

Method of administration: Oral

4.3 Contraindication:

Loratadine products are contraindicated in patients who have shown hypersensitivity or idiosyncrasy to their component.

4.4 Special warnings and special precautions for use:

1. Drugs known to inhibit hepatic metabolism should be co-administered with caution until definitive interaction studies can be completed. The number of subjects who concomitantly received macrolide antibiotics, ketoconazole, cimetidine, ranitidine, or theophylline along with loratadine in controlled clinical trials is too small to rule out possible drug interactions.

2. Patients with severe liver impairment or renal impairment (creatinine clearance < 30ml/min) should be administered a lower initial dose because they may have reduced clearance of loratadine, an initial dose of 5mg once daily or 10mg every other day is recommended.
3. Safety and efficacy of loratadine in children < 2 years have not been established yet.

4.5 Interaction with other FPPs and other forms of interaction:

1. When administered concomitantly with alcohol, loratadine has no potentiate effects as measured by psychomotor performance studies.
2. Ketoconazole, erythromycin, and cimetidine may increase plasma-loratadine concentration, but without clinically significant changes (including electrocardiographic).
3. Plasma concentration of loratadine possibly increased by amprenavir.
4. Other drugs known to inhibit hepatic metabolism should be co-administered with caution until definitive interaction studies can be completed.

4.6 Pregnancy and lactation:

There are no adequate and controlled studies to date using loratadine in pregnant women, so it should be used during pregnancy only when the potential benefits justify the possible risks to the fetus.

Caution should be exercised when loratadine is administered in a nursing woman because it is distributed readily into breast milk. Due to the increased risk of antihistamines for infants, particularly newborns and premature infants, a decision should be made whether to discontinue nursing or discontinue the drug.

4.7 Effects on ability to drive and use machines

Although drowsiness is rare, nevertheless patients should be advised that it can occur and my affect skilled tasks (e.g. driving).

4.8 Undesirable effects

The incidence of most commonly reported adverse effects-fatigue, sedation and headache associated with loratadine tablets has been comparable to that of placebo. In trials, loratadine has shown no

clinically significant sedative or anticholinergic properties. During the marketing of loratadine, alopecia has been reported.

4.9 Overdose:

To date overdosage has not occurred with loratadine. A single acute ingestion of 160mg produced no adverse effects. In the event of overdosage, treatment, which should be started immediately, is symptomatic and supportive. Treatments include gastric lavage and/or activated charcoal, induction of emesis with ipecac syrup, close observation and general supportive measures. Loratadine is not cleared by hemodialysis to any appreciable extent. After an emergency, the patient should continue to be medically monitored.

5. PHARMACOLOGICAL PROPERTIES:

5.1 Pharmacodynamic properties

Antihistamine used in the treatment of allergy acts by competing with histamine for H1-receptor sites on effector cells. They, thereby, prevent but do not reverse responses mediated by histamine alone. Antihistamines do not block histamine release, but they antagonize in varying degree, most of the pharmacological effects of histamine, including urticaria and pruritus. Also, the anticholinergic actions of most antihistamines provide a drying effect in the nasal mucosa, but loratadine has no significant anticholinergic activity. Loratadine is a long-acting antihistamine. It has been characterized as a specific, selective peripheral H1-receptor antagonist and has been referred to as a relatively “non-sedating” or second generation antihistamine.

5.2 Pharmacokinetic properties:

1. Following single administration, loratadine exhibits antihistamines effects beginning within ½ - 1 hour, reaching a maximum at 8-10 hours, and lasting in excess of 24 hours.
2. Distribution of loratadine has not been fully characterized. Protein binding of loratadine is about 97-99%. It appears to distribute poorly or not appreciably into the CNS at usual dosage. Small amount of it appears to be distributed into milk.
3. The mean elimination half-life is 7.8-11 hours.
4. Loratadine undergoes extensive metabolism by Cytochrome P450. The major metabolite, descarboethoxyloratadine (desloratadine) has potent antihistamine activity.

Most of a dose is excreted equally in the urine and faeces, mainly in the form of metabolites.

5.3 Preclinical safety data:

No information available.

6. Pharmaceutical particulars:

6.1 List of excipients:

Lactose Monohydrate

Povidone

Potato Starch

Polyethylene Glycol

Magnesium Stearate

Sodium Starch Glycolate

Purified Water

6.2 Incompatibilities:

No information available.

6.3 Shelf life:

3 years from the date of manufacture.

6.4 Special precautions for storage:

Store at temperature below 30°C. Protect from light and moisture.

6.5 Nature and contents of container

Blister Pack of 10’s x 10

6.6 Instructions for use and handling and disposal:

None has been mentioned.

7. MARKETING AUTHORIZATION HOLDER

Y. S. P. INDUSTRIES (M) SDN. BHD.
Lot 3, 5 & 7, Jalan P/7, Section 13,
Kawasan Perindustrian Bandar Baru Bangi,
43000 Kajang, Selangor Darul Ehsan,
Malaysia.

8. MARKETING AUTHORIZATION NUMBER

04738/07022/REN/2019

9. DATE OF ~~FIRST AUTHORIZATION~~ / RENEWAL OF THE AUTHORIZATION:

16 Dec 2019

10. DATE OF REVISION OF THE TEXT:

28 July 2023