1.3 PRODUCT INFORMATION
1.3.1 SUMMARY OF PRODUCT CHARACTERISTICS (SMPC)

1. NAME OF THE MEDICINAL PRODUCT
LORATADINE TABLETS USP 10 MG (LORAWOOD)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each uncoated tablet contains

Loratadine USP	10 mg
Excipients	Q.S

3. PHARMACEUTICAL FORM
Tablet for oral use

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
Loratadine Tablets are 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: 10 mg once daily. The tablet may be taken without regard to mealtime.
Children 2 to 12 years of age with:
Body weight more than 30 kg: 10 mg once daily.
Body weight 30 kg or less: These tablets are not suitable in children with a body weight less than 30 kg.
Efficacy and safety of Loratadine Tablets in children under 2 years of age has not been established.
No dosage adjustments are required in the elderly or in patients with renal insufficiency.

Method of administration

Oral use. The tablet may be taken without regard to mealtime.

4.3 Contraindications
Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

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 Interaction with other medicinal products and other forms of interaction

other natural substances such as garlic, fish oil and turmeric

4.6 Pregnancy and lactation

Pregnancy

A large amount of data on pregnant women (more than 1000 exposed outcomes) indicate no malformative nor foeto/ neonatal toxicity of loratadine. As a precautionary measure, it is preferable to avoid the use of loratadine during pregnancy.

Breast-feeding

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

Fertility

There is no data available on male and female fertility.

4.7 Effects on ability to drive and use machines

In clinical trials that assessed driving ability, no impairment occurred in patients receiving loratadine. Loratadine has no or negligible influence on the ability to drive and use machines. However, patients should be informed that very rarely some people experience drowsiness, which may affect their ability to drive or use machines.

4.8 Undesirable effects

A very rare side effects found like Hypersensitivity reaction, Dizziness, Convulsion, Tachycardia, Palpitation, Nausea, Dry mouth, Gastritis, Abnormal hepatic Function, fatigue etc

4.9 Overdose

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

5. PHARMACOLOGICAL PROPERTIES

Pharmacodynamic Property:

Pharmacotherapeutic group: antihistamines – H_1 antagonist, ATC code: R06A X13.

Mechanism of action: Loratadine, the active ingredient in Loratadine Tablets, is a tricyclic antihistamine with selective, peripheral H_1-receptor activity.

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 major metabolite desloratadine (DL) moderately bound (73% to 76%) to plasma proteins.

Biotransformation.

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.

5.1 Preclinical safety data

Preclinical data reveal no special hazard based on conventional studies of safety, pharmacology, repeated dose toxicity, genotoxicity and carcinogenic potential.

In reproductive toxicity studies, no teratogenic effects were observed. However, prolonged parturition and reduced viability of offspring were observed in rats at plasma levels (AUC) 10 times higher than those achieved with clinical doses.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Lactose monohydrate
Maize starch
Purified Water
Colloidal Silicon Dioxide
Magnesium stearate

6.2 Incompatibilities

None

6.3 Shelf life

36 Months

6.4 Special precautions for storage

Store below 30°C.

Protect from light & Moisture.

Keep out of reach of children.

6.5 Nature and contents of container

10 tablets are packed in Alu-Pvc blister pack. Such 10 Blisters are packed in printed carton along with packaging insert.

6.6 Special precautions for disposal and other handling

Store in the original package in order to protect from light and moisture.

7. MARKETING AUTHORISATION HOLDER

HALEWOOD LABORATORIES PVT. LTD
PLOT NO. 319, PHASE II. G.I.D.C., VATVA,
AHMEDABAD 382 445, GUJURAT, INDIA

8. MARKETING AUTHORISATION NUMBER(S)

===Not Applicable===

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

===Not Applicable===

10. DATE OF REVISION OF THE TEXT

===Not Applicable==