1.3.1.1.2 Clean Proposed Professional Information

Clean Proposed Professional Information

SCHEDULING STATUS

S2

1. NAME OF THE MEDICINE

LORFAST

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each **LORFAST** tablet contains 10 mg loratadine (micronized)

Sugar free

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet

Round, flat, smooth, white tablet with beveled edges, a breakline on one side, and “LFT” embossed on the other side.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

LORFAST is indicated for the relief of symptoms associated with seasonal allergic rhinitis and chronic urticarial.

4.2 Posology and method of administration

Posology

Adults: one tablet a day

Use of **LORFAST** should be limited to 14 days.

Method of administration

Oral use.

4.3 Contraindications

- **LORFAST** should not be used in patients with known hypersensitivity to loratadine or any of the excipients of **LORFAST** (listed in section 6.1).
- Cross sensitivity to other antihistamines.
- Porphyria.

4.4 Special warnings and precautions for use

The safety of LORFAST in the elderly has not been established.

The safety of LORFAST in children under two years has not been established.

LORFAST should be used with caution in patients:

- severe liver impairment, as reduced clearance of loratadine may occur. Dosage adjustment may be needed.
- Renal impairment - A lower starting dose should be used. In patients with chronic renal impairment, (creatinine clearance of 30 ml/minute or less), both oral bioavailability and peak plasma concentrations of loratadine may be increased. However, the elimination half-life of loratadine and its active metabolite appear to be similar to those individuals with normal renal function.

The use of **LORFAST** should be discontinued approximately 48 hours prior to skin testing procedures since it may prevent or diminish otherwise positive reactions to dermal reactivity indicators.

LORFAST shall be used with caution when the following medical conditions exist and/or in patients using other medicines metabolised by the cytochrome P-450 system: Emphysema; prostatic hypertrophy; narrow angle glaucoma; cardiovascular disorder; epilepsy; and during acute attacks of asthma.

4.5 Interaction with other medicines 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. Concomitant use of **LORFAST** with inhibitors of cytochrome P-450 enzyme system such as cimetidine, ketoconazole, clarithromycin and erythromycin may increase the plasma concentrations of **LORFAST**.

4.6 Fertility, pregnancy and lactation

Pregnancy

Safety and efficacy in pregnancy and lactation have not been established.

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. As a precautionary measure, it is preferable to avoid the use of loratadine tablet during pregnancy.

Breastfeeding

Loratadine and its metabolites have been detected in breast milk. Small amounts of **LORFAST** entering breast milk may cause drowsiness or excitement in infants. Therefore, the use of **LORFAST** is not recommended in breast-feeding women.

Fertility

There are no data available on male and female fertility.

4.7 Effects on ability to drive and use machines

LORFAST lacks significant sedative effects. Patients should, however be warned that a small number of individuals may experience sedation. It is therefore advisable to determine individual response before driving or performing complicated tasks. This effect may be compounded by the simultaneous intake of alcohol or other central nervous system depressants.

4.8 Undesirable effects

System Order Class	**Frequent**	**Less frequent**	**Frequency unknown**
Immune system disorders		**Anaphylaxis including angioedema**	
Nervous system disorders	**Headache, somnolence, confusion, nightmares**	**Sedation, nervousness**	**Dizziness, convulsions**
Eye disorders	**Blurred vision**		

Cardiac disorders		**Tachycardia and palpitation**	
Gastrointestinal disorders	**Dry mouth, nausea and gastritis**		
Hepato-biliary disorders		**Abnormal hepatic function**	
Skin and subcutaneous tissue disorders		**Rash, alopecia**	
Metabolism and nutrition disorders	**Increased appetite**		
General disorders and administration site conditions	**Fatigue**		

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/

4.9 Overdose

Symptoms of overdose that have been reported are somnolence, tachycardia and headaches. In children, extrapyramidal manifestations and palpitations have been reported.

Treatment of overdose

Treatment is symptomatic and supportive. After overdose of **LORFAST**, the stomach should be emptied immediately by inducing emesis or gastric lavage. Administration of activated charcoal after emesis may be useful in preventing absorption of **LORFAST**. Saline cathartics may be of value to rapidly dilute bowel contents. **LORFAST** is not cleared by haemodialysis.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and Class: A 5.7.1 Antihistaminics.

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

Loratadine is a second generation histamine (H_1) receptor antagonist. Loratadine exerts its action by competing with histamine for H_1 -receptor sites on effector cells. It prevents, but does not reverse responses mediated by histamine. Loratadine does not cross the blood-brain barrier to any extent.

5.2 Pharmacokinetic properties

After oral administration, loratadine is well absorbed from the gastro-intestinal tract and peak plasma concentrations are reached within 1.5 hours. Ingestion of food may enhance the absorption of loratadine. Loratadine undergoes extensive first pass metabolism via the cytochrome P-450 system. The major metabolite, desloratadine, is active. Loratadine is 97 % protein bound, while desloratadine is less extensively protein bound (73

% to 77 %). The mean elimination half-lives for loratadine and desloratadine are 8.4 and 28 hours respectively.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- calcium hydrogen phosphate,
- colloidal anhydrous silica,
- magnesium stearate,
- maize starch,
- purified talc
- purified water
- sodium starch glycollate.

6.2 Incompatibilities

Not Applicable

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store at or below 25 °C. Protect from moisture.

6.5 Nature and contents of container

10's: Blister pack (composed of transparent PVC and silver coloured aluminium foil backing) of 10 tablets in a carton.

30's: Three Blister packs (composed of transparent PVC and silver coloured aluminium foil backing) of 10 tablets each, in a carton.

100's: Two blister packs (composed of transparent PVC and silver coloured aluminium foil backing) of 50 tablets in a carton.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

RANBAXY PHARMACEUTICALS (PTY) LTD.

14 LAUTRE ROAD

STORMILL EXT.1

ROODEPOORT 1724

SOUTH AFRICA

8. REGISTRATION NUMBER(S)

A38 / 5.7.1/ 0621

S2 BOT 0801397 (Botswana) (10's & 30's)
NS1 07/5.7.1/00752 (Namibia)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

29 JULY 2005

10. DATE OF REVISION OF THE TEXT

08 December 2025