PATIENT INFORMATION LEAFLET

SCHEDULING STATUS **S2**

LORFAST

Loratadine

Sugar free

Read all of this leaflet carefully before you start taking LORFAST

LORFAST is available without a doctor's prescription, for you to treat a mild illness. Nevertheless you still need to use LORFAST carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share LORFAST with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

What is in this leaflet

1. What LORFAST is and what it is used for

2. What you need to know before you take LORFAST How to take LORFAST

3. Possible side effects

4. How to store LORFAST

5. Contents of the pack and other information

1. What LORFAST is and what it is used for

LORFAST is an antihistamine use to relieve the symptoms of hay fever and other types of allergy. It works by preventing the effects of a substance called histamine, which is produced by the body. LORFAST is also used in the treatment of chronic urticaria, which is a persistent hive-like rash.

2. What you need to know before you take LORFAST

Do not take LORFAST:

- if you are hypersensitive (allergic) to loratadine, or to any of the other ingredients of LORFAST (listed in section 6).
- If you have ever had any unusual or allergic reaction to antihistamines.
- If you are having a rare blood pigment disorder known as porphyria.

Warnings and precautions

Take special care with LORFAST:

- if you have liver disease.
- if you have kidney disease.
- if you have emphysema (shortness of breath, with a cough).
- if you have an enlarged prostate.
- if you have narrow angle glaucoma (high pressure in the eye).
- if you have heart problems.
- if you have a medical history of seizures.
- If you suffer from acute asthma attacks.
- if you are scheduled to have any skin tests for allergies you should not take **LORFAST** for 48 hours before having these tests, because **LORFAST** may affect tests results.

Other medicines and LORFAST

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

The side effects of LORFAST may increase when used together with medicines that alter the performance of some enzymes responsible for drug metabolism in the liver. These medicines include cimetidine (medicine used to reduce stomach acid production), ketoconazole (medicine used to treat fungal infections), clarithromycin and erythromycin (antibiotics used to treat various

bacterial infections). Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines. This includes medicines taken without a prescription.

LORFAST with alcohol

LORFAST has been shown to add to the effects of an alcoholic drink.

Pregnancy, breast-feeding and fertility

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking LORFAST.

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

Do not take LORFAST of you are breastfeeding. Loratadine is excreted in breast milk.

Driving and using machines

At the recommended dose**,** LORFAST is not expected to cause you to be drowsy or less alert. However, very rarely some people experience drowsiness, which may affect their ability to drive or use machines.

Test your response before driving or performing complicated tasks. You can suffer sedation if you take alcohol or other central nervous system depressant at the same time as taking **LORFAST.**

HOW TO TAKE LORFAST

Do not share medicines prescribed for you with any other person. Always take LORFAST exactly as described in the leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor or pharmacist if you are not sure.

- The usual dose of LORFAST is one tablet taken once daily for adults.

If you take more LORFAST than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take LORFAST

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

LORFAST can have side effects.

Not all side effects reported for LORFAST are included in this leaflet. Should your general health worsen of if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking LORFAST and tell your doctor immediately or go to the casualty department at your nearest hospital:

- rash
- allergic reactions
- anaphylaxis (serious life-threatening allergic reaction)

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to LORFAST. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- increase rate of heart beat
- palpitations (unpleasant sensation of irregular and/or forceful beating of the heart)

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- headache,
- sleepiness,
- confusion,
- nightmares,
- blurred vision,
- dry mouth,
- nausea (feeling sick),
- gastritis (inflammation, swelling and redness of the stomach lining),
- increased appetite,
- fatigue (tiredness).

Less frequent side effects:

- sedation,
- nervousness,
- hair loss,

If you notice any side effect not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist, or nurse. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of LORFAST.

5. How to store LORFAST

- Store LORFAST tablets at or below 25°C.
- Protect from moisture.
- Keep your tablets in the original blister packs.

- Do not take LORFAST tablets after the expiry date on the carton.
- Return unused or expired medicines to your pharmacist for safe disposal.
- Store all medicines out of reach of children.

6. Contents of the pack and other information

What LORFAST contains

The active substance is loratadine.

The other ingredients are**:**

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

What LORFAST looks like and contents of the pack

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

Contents of the pack:

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

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

Holder of Certificate of Registration

RANBAXY PHARMACEUTICALS (PTY) LTD.

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EXT. 1

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