Approved Patient Information Leaflet for Medicines for Human Use:

AUSTELL LORATADINE 10 mg

SCHEDULING STATUS

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PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

AUSTELL LORATADINE 10 mg tablets.

Read all of this leaflet carefully before you start to take AUSTELL LORATADINE

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **AUSTELL LORATADINE** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT AUSTELL LORATADINE CONTAINS

Each **AUSTELL LORATADINE** is tablet that contains 10 mg of loratadine as the active ingredient.

The other ingredients are: Lactose monohydrate, magnesium stearate and maize starch.

Contains sugar (lactose monohydrate 188,5 mg/tablet).

2. WHAT AUSTELL LORATADINE IS USED FOR

AUSTELL LORATADINE is used for:

- the relief of symptoms associated with allergic rhinitis (for example, hay fever), such as sneezing, runny or itchy nose, and burning or itchy eyes,
- for the relief of symptoms of urticaria (a skin condition caused by an allergy). These

symptoms include itching and hives.

3. BEFORE YOU TAKE AUSTELL LORATADINE

Do not take AUSTELL LORATADINE if you:

- if you are hypersensitive (allergic) to loratadine or any of the ingredients of **AUSTELL LORATADINE,**
- if you are pregnant or breastfeeding.

If you are uncertain whether any of these apply to you, please discuss this with your doctor or pharmacist before taking **AUSTELL LORATADINE**.

Take special care with AUSTELL LORATADINE

- if you have liver disease,
- if you are scheduled to have any skin tests for allergies. Do not take **AUSTELL LORATADINE** for two days before having these tests because it may affect the test results,
- if you are concerned with gaining weight as **AUSTELL LORATADINE** may cause weight gain.

Children and adolescents

Do not give **AUSTELL LORATADINE** to children younger than 6 years old or to children who weigh 30 kg or less.

Children under 2 years of age: The safety and efficacy of **AUSTELL LORATADINE** has not been established.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby, please consult your healthcare provider for advice before taking **AUSTELL LORATADINE.**

AUSTELL LORATADINE should not be used if you are pregnant or breastfeeding.

Driving and using machinery

At the recommended dose, **AUSTELL LORATADINE** is not expected to affect your ability to drive or use machines. Although most people do not experience drowsiness, it is recommended not to engage in activities requiring mental alertness, such as driving a car or operating machinery until you have established your own response to the medicine.

Important information about some of the ingredients of AUSTELL LORATADINE

AUSTELL LORATADINE contains lactose. Patients with the rare hereditary conditions of lactose or galactose intolerance should not take **AUSTELL LORATADINE.**

Using other medicines with AUSTELL LORATADINE

Always tell your health care provider if you are taking any other medicine (this includes complementary or traditional medicines).

The side effects of **AUSTELL LORATADINE** may increase when used together with medicines that alter the performance of some enzymes responsible for drug-metabolism in the liver.

4. HOW TO USE AUSTELL LORATADINE

Do not share medicines prescribed for you with any other person.

Always take **AUSTELL LORATADINE** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Adults and children 6 years and older who weigh more than 30 kg:

One tablet once daily.

Do not give **AUSTELL LORATADINE** to children under 2 years or who weigh 30 kg or less.

If you have severe liver problems your doctor or pharmacist may start you on 5 mg once daily and then 10 mg on every alternate day.

If you have the impression that the effect **AUSTELL LORATADINE** is too strong or too weak, tell your doctor or pharmacist.

If you use more AUSTELL LORATADINE than you should

You may experience an increase in side effects and their frequency.

In the event of over-dosage, consult your doctor or pharmacist immediately. If neither is available, contact the nearest hospital or poison control centre.

Take this leaflet and any remaining tablets with you, so that the doctor knows what you have taken.

If you forget to take your dose of AUSTELL LORATADINE

It is important to use this medicine as prescribed by your doctor.

If you miss a dose, take it as soon as possible. However, if it is almost time for the next dose, skip the missed dose and go back to your regular dosing schedule. Do not use a double dose to make up for the forgotten dose.

If you stop using AUSTELL LORATADINE

If you want to stop using **AUSTELL LORATADINE,** talk to your doctor first.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

5. POSSIBLE SIDE EFFECTS

AUSTELL LORATADINE can have side effects. Not all side effects reported for AUSTELL LORATADINE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking AUSTELL LORATADINE please consult your health care provider for advice.

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

- anaphylaxis (allergic reaction) cough, difficulty swallowing, dizziness, fast heartbeat, hives, skin rash,
- itching, puffiness or swelling of the eyelids or around the eyes, face, lips of tongue,
- shortness of breath, tightness in chest, unusual tiredness or weakness, wheezing.

These are all very serious side effects. If you have them, you may have had a serious reaction to **AUSTELL LORATADINE.** 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:

Frequent (in adults and children over 12 years of age):

- drowsiness,
- headache,
- increased appetite,
- difficulty sleeping.

Frequent (in children aged 2 to 12 years):

- headache,
- nervousness,
- tiredness.

Less frequent:

- severe allergic reaction (including swelling),
- dizziness,
- convulsion,
- fast or irregular heartbeat,
- nausea (feeling sick),
- dry mouth,
- upset stomach,
- liver problems,
- hair loss,
- rash,
- tiredness.

Frequency unknown

- weight gain.

6. STORING AND DISPOSING OF AUSTELL LORATADINE

- Keep this medicine in a dry place at or below 25°C. Protect from moisture.
- Store in the original packaging.
- Do not use **AUSTELL LORATADINE** after the expiry date printed on the pack.
- Return any expired or unused medicine to your pharmacist for safe disposal. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

7. PRESENTATION OF AUSTELL LORATADINE

Clear transparent PVC/PVdC aluminium blister packs of 7, 10, 30 or 250 tablets.

Bulk: White HDPE bottles of 100 tablets.

Not all pack sizes may be marketed.

8. IDENTIFICATION OF AUSTELL LORATADINE

White, oval shaped tablets with a score line on one side and plain on other side.

9. REGISTRATION NUMBER

A38/5.7.1/0380

10. THE NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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11. DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET

Date on the registration certificate: 17 February 2016