PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

This medicine is dispensed without a doctor's prescription

Loratadin

Tablets, 10 mg

Each tablet contains: loratadine 10 mg
Inactive ingredients and allergens in the preparation - see section 6 "Additional information" and section 2 "Important information about some ingredients of the medicine".

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about **Loratadim**. If you have any other questions, refer to the doctor or the pharmacist.

You should take this medicine in accordance with the instructions in the dosage section of this leaflet. Consult the pharmacist if you have further questions. Refer to the doctor if signs of the ailment (symptoms) worsen or do not improve.

1. What is the medicine intended for?

Loratadim is used for treatment of allergic rhinitis and its accompanying symptoms, such as sneezing, runny or itchy nose, and burning or itching eyes, and also for treatment of skin allergy, hives (urticaria).

How does the medicine work?

Loratadim relieves allergy symptoms by preventing the effects of a substance called histamine, which is produced by the body when you are allergic to something.

Therapeutic group: the medicine contains the active ingredient loratadine, a medicine that belongs to a group called "anti-histamines".

2. Before using the medicine:

☒ Do not use this preparation if:

- You are allergic (sensitive) to loratadine or to any of the other ingredients of this medicine (for a list of inactive ingredients, see section 6).

❗ Special warnings regarding the use of Loratadim

Before treatment with Loratadim, tell your doctor, pharmacist or nurse if:

- You are suffering from hepatic disease.
- You are about to undergo skin tests for allergies. Do not take **Loratadim** during the two days before these tests because this medicine may affect the test results.

If any of the abovementioned circumstances apply to you or if you are not sure, consult a doctor, a pharmacist or a nurse before taking **Loratadim**.

Children and adolescents

Loratadim should not be given to children under 6 years of age or to children who weigh less than 30 kg. There are other forms of administration which are more suitable for children under 6 years of age or those who weigh less than 30 kg.

Children under 2 years of age:

There is no data to prove the safety and efficacy of **Loratadim** in this age group.

❗ Drug-drug interactions

If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, inform the doctor, pharmacist or nurse.

The chance for side effects is higher when you take **Loratadim** together with medicines that affect the activity of liver enzymes that are responsible for metabolizing medicines in the liver. However, in clinical studies no increase in side effects has been observed despite taking medicines that affect the activity of these enzymes.

Use of Loratadim and food

Loratadim may be taken with or without food.

Use of Loratadim and alcohol consumption

Loratadim has not been found to increase the effects of alcoholic beverages.

Pregnancy, breastfeeding and fertility

If you are pregnant, think that you might be pregnant or are planning to become pregnant, consult the doctor or pharmacist before taking this medicine. According to existing data, no damage to the fetus or newborn baby has been observed following use of this preparation, but it is better to avoid using this preparation during pregnancy.

The active ingredient in the medicine, loratadine, is secreted into breast milk, and therefore use of the medicine is not recommended for breastfeeding women.

Driving and operating machinery

According to clinical studies, driving ability was not impaired in patients taking loratadine. At the recommended dosage, **Loratadim** is not expected to cause drowsiness or decreased alertness.

However, in very rare cases, some people feel drowsiness which may affect their ability to drive or operate machinery.

Important information about some ingredients of the medicine

The medicine contains lactose. If you have been told by your doctor that you have an intolerance to certain sugars, contact your doctor before taking this medicine.

3. How should you use Loratadim?

Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation.

The generally accepted dosage is:

Adults and children aged 6 years of age or older with body weight above 30 kg:

One tablet once daily with a glass of water, with or without food.

It is important to know your child's body weight to ensure he/she receives the correct dose of the medicine. If you are unsure about your child's weight, measure his/her weight before administering the preparation.

Body weight 30 kg or less:

Loratadim should not be administered. There is another form of administration (syrup), which is more suitable for children under 6 years of age or who weigh 30 kg or less.

Loratadim is not intended for use in children under two years of age or those who weigh 30 kg or less.

Adults and children with severe liver problems:

If you have severe liver problems, contact the doctor or pharmacist, who may recommend taking the recommended dose every other day with a glass of water, with or without food. If this applies to you, you must follow their instructions.

Do not exceed the recommended dose.

The tablet can be halved if needed.

If you accidentally took a higher dose

contact your doctor or pharmacist immediately. No severe problems are expected, but you may suffer from headaches, rapid heartbeat or feeling of drowsiness.

If you took an overdose or if a child swallowed this medicine by mistake, go to the doctor or the emergency room of the hospital immediately and take the package of the medicine with you.

If you forgot to take Loratadim at the required time, take a dose as soon as you remember and then continue according to the regular schedule. Under any circumstances, do not take a double dose in order to compensate for a forgotten dose.

Do not take medicines in the dark! Check the label and the dosage every time you take the medicine. Wear glasses if you need them.

If you have any other questions regarding use of the medicine, consult the doctor or the pharmacist.

4. Side effects:

As with any medicine, use of **Loratadim** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

The most common side effects reported in adults and children over 12 years of age are:

- Drowsiness
- Headache
- Increased appetite
- Difficulty sleeping

The most common side effects reported in children over 2-12 years of age are:

- Headache
- Nervousness
- Tiredness

Very rare side effects (may affect up to one in 10,000 people) have also been observed during use of loratadine:

- Severe allergic reaction (including swelling)
- Dizziness
- Convulsions
- Rapid or irregular heartbeat
- Nausea
- Dry mouth
- Digestive disturbances
- Liver problems
- Hair loss
- Rash
- Tiredness

Side effects with unknown frequency:

- Weight gain

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult with the doctor.

Reporting side effects:

Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: https://sideeffects.health.gov.il/

5. How to store the medicine?

Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.

Do not use **Loratadim** after the expiry date (exp.) appearing on the package. The expiry date refers to the last day of that month.

Storage: store at a temperature lower than 25°C.

Do not take this medicine if you notice any change in the tablet's appearance.

Do not discard medicines in the wastewater or a domestic trash can. Ask the pharmacist how to dispose of medicines no longer in use. These measures will help protect the environment.

6. Additional information:

In addition to the active ingredient, the medicine also contains:

Lactose, pregelatinized maize starch, Sodium starch glycolate, magnesium stearate.

What does the medicine look like and what are the contents of the package: A white to off-white tablet, scored on both sides.

Approved package sizes: 7, 10 or 20 tablets per pack. Not all package sizes may be marketed.

Manufacturer/license holder and address: CTS Chemical Industries Ltd., 3 Hakidma St., Kiryat Malachi.

This leaflet was reviewed and approved by the Ministry of Health in 08/2015 and has been updated in accordance with the Ministry of Health instructions in 07/2020.

Registration number of the medicine in the national drug registry of the Ministry of Health: 1370930171

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