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

The medicine is dispensed with a doctor's prescription only

Des-loratadim 5 mg tablets

Each tablet contains: desloratadine 5 mg
For a list of inactive ingredients, see section 6 "Additional information".
Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any other questions, refer to the doctor or the pharmacist.
This medicine has been prescribed for your treatment. Do not pass it on to others. It may harm them, even if their medical condition seems similar to yours.
This medicine is intended for adults and adolescents 12 years old and older.

1. What is the medicine intended for?

Des-loratadim is an antiallergy medicine which does not cause drowsiness. It helps to control the allergic reaction and its symptoms.
This medicine relieves symptoms associated with allergic rhinitis (inflammation of the nasal cavities caused by allergy, for example, hay fever or allergy to dust mites) in adults and adolescents 12 years old and older. These symptoms include sneezing, runny or itchy nose, palate itching and itchy, red or watery eyes.
Des-loratadim is also used to relieve symptoms associated with hives (urticaria: a skin phenomenon caused by an allergy). These symptoms include itching and rash.
These symptoms are relieved for an entire day, which helps you to return to your regular daily activities and your regular sleep.
Therapeutic class: H_1 receptor antagonists – antihistamines.

2. Before using the medicine:

☒ Do not use this medicine if:

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

❗ Special warnings regarding the use of the medicine: Before treatment with Des-loratadim, inform the doctor if:
- You are suffering from impaired renal function.
- You have a medical or family history of convulsions.

❗ Use in children and adolescents:
This medicine is not intended for children under 12 years of age.

❗ Drug interactions:
If you are taking or have recently taken other medicines, including non-prescription medicines and food supplements, tell the treating physician or the pharmacist.
There are no known drug interactions between Des-loratadim and other medicines.

❗ Use of the medicine and food:
The medicine may be taken with or without a meal.

❗ Use of Des-loratadim and alcohol:
Caution should be maintained when taking Des-loratadim with alcohol.

❗ Pregnancy, breastfeeding and fertility:
If you are pregnant or breastfeeding, think that you might be pregnant or are planning to become pregnant, consult your physician or a pharmacist before taking this medicine.
It is not recommended to take Des-loratadim if you are pregnant or breastfeeding.
No information is available regarding male/female fertility.

❗ Driving and operating machinery:
At the recommended dosage, Des-loratadim is not expected to affect the ability to drive and to operate machinery.
Although most people do not experience drowsiness, it is recommended to avoid activities that require alertness, such as driving a car or operating machinery, until you have established your reaction to the medicine.

3. How should you use the medicine?

Always use Des-loratadim according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation.
The dosage and treatment regimen will be determined by the doctor only.
Adults and adolescents (12 years old and older):
The usually recommended dosage is one tablet once a day with water, with or without food.
Do not exceed the recommended dose.
Method of administration – this medicine is intended to be taken orally. The tablet should be swallowed whole.
Crushing/halving/chewing
Do not chew! The tablet is intended to be swallowed. Do not halve, as there is no score line. No information is available regarding crushing/pulverizing the tablets.
Duration of treatment:
Your physician will decide what type of allergic rhinitis you are suffering from and for how long you should take Des-loratadim.
- If your allergic rhinitis is periodic (symptoms experienced for less than 4 days a week or for less than 4 weeks), your physician will recommend you a treatment plan dependent on the evaluation of the history of your illness.
- If your allergic rhinitis is persistent (symptoms experienced for 4 days a week or more and for more than 4 weeks), your physician may recommend you to take the treatment for a longer period.
- For urticaria (hives), the duration of treatment may vary from one patient to another, therefore, you should follow your physician's instructions.

If you have accidentally taken a higher dosage of Des-loratadim:
You should take Des-loratadim only as prescribed for you. No serious problems are expected if you have accidentally taken an overdose. However, if you have taken more Des-loratadim than what you have been prescribed, inform your physician or pharmacist immediately.
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 the medicine:
If you have forgotten to take the medicine at the scheduled time, take a dose as soon as possible and then return to your regular schedule. Do not take a double dose in order to compensate for the dose that you forgot to take.
Follow the treatment as recommended by the doctor.
Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor or pharmacist.
Do not take medicines in the dark! Check the label and the dose 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, using Des-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.
Stop taking the medicine and seek urgent medical help immediately if you observe any of the following severe side effects:
Severe allergic reactions (difficulty breathing, wheezing, itching, urticaria and swelling).
During marketing of Des-loratadim, cases of such severe allergic reactions have been reported very rarely.
In clinical trials performed among adults taking a medicine containing the active ingredient desloratadine, side effects similar to those seen in patients who received placebo were reported. However, fatigue, dry mouth and headaches were reported more frequently in patients treated with the medicine than in patients treated with placebo. In adolescents, headache was reported as the most common side effect.

In clinical trials performed among patients taking a medicine containing the active ingredient desloratadine, the following side effects were reported:
Common side effects – side effects that occur in 1-10 out of 100 users:
- Tiredness.
- Dry mouth.
- Headache.

During marketing of Des-loratadim, the following side effects have been reported:
Very rare side effects – side effects that occur in less than one out of 10,000 users:
- Severe allergic reactions.
- Rash.
- Strong or irregular heartbeats.
- Fast heartbeat.
- Abdominal pain.
- Nausea.
- Vomiting.
- Abdominal discomfort.
- Diarrhea.
- Dizziness.
- Drowsiness.
- Inability to sleep.
- Myalgia (muscle pain).
- Hallucinations.
- Seizures.
- Restlessness accompanied by increased body movement.
- Hepatitis.
- Abnormal values in liver function tests.

Side effects with unknown frequency – side effects whose frequency has not yet been determined:
- Abnormal weakness.
- Yellowing of the eyes and/or the skin.
- Increased skin sensitivity to the sun, even when it's cloudy, and to UV light, e.g. UV light in a solarium (tanning salon).
- Changes in the way the heart beats.
- Abnormal behavior.
- Aggressiveness.
- Weight gain, increased appetite.
- Depressed mood.
- Dry eyes.

Children
Side effects with unknown frequency – side effects whose frequency has not yet been determined:
- Slow heartbeat.
- Changes in the way the heart beats.
- Abnormal behavior.
- Aggressiveness.

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 your 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 the medicine after the expiry date (EXP) appearing on the package. The expiry date refers to the last day of that month.
Store in the original packaging at a temperature below 25°C.

6. Additional information:

In addition to the active ingredient, the medicine also contains:
Microcrystalline cellulose, Pregelatinized Starch, Opadry White OY-S-28917, Magnesium Stearate, Macrogol 6000, FD&C Blue No.2 Lake.
What does the medicine look like and what are the contents of the package:
Des-loratadim tablets are coated and biconvex. Their color is light blue. They are packed in blisters in packages of 5, 10, 14, 15, 20 or 30 tablets. Not all package sizes may be marketed.
Manufacturer and marketing authorization holder:
CTS Chemical Industries Ltd., 3 Hakidma st., Kiryat Malachi, 8305769.
This leaflet was revised in November 2022 in accordance with the Ministry of Health guidelines.
Registration number of the medicine in the National Drug Registry of the Ministry of Health:
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