

PACKAGE LEAFLET : INFORMATION FOR THE USER

Ladodin 5 mg film-coated tablets Desloratadine

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Ladodin is and what it is used for
2. Before you take Ladodin
3. How to take Ladodin
4. Possible side effects
5. How to store Ladodin
6. Further information

1. WHAT LADODIN IS AND WHAT IT IS USED FOR

Ladodin is an antiallergy medicine that does not make you drowsy. It helps control your allergic reaction and its symptoms.

Ladodin relieves symptoms associated with allergic rhinitis (inflammation of the nasal passages caused by an allergy, for example, hay fever or allergy to dust mites). These symptoms include sneezing, runny or itchy nose, itchy palate, and itchy, red or watery eyes.

Ladodin is also used to relieve the symptoms associated with urticaria (a skin condition caused by an allergy). These symptoms include itching and hives.

Relief of these symptoms lasts a full day and helps you to resume your normal daily activities and sleep.

2. BEFORE YOU TAKE LADODIN

Do not take Ladodin

- if you are allergic (hypersensitive) to desloratadine, to any of the other ingredients of Ladodin or to loratadine.

Ladodin is indicated for adults and adolescents (12 years of age and older).

Take special care with Ladodin

- if you have poor kidney function.

If this applies to you, or if you are not sure, please check with your doctor before taking Ladodin.

Taking other medicines

There are no known interactions of Ladodin with other medicines.

Taking Ladodin with food and drink

Ladodin may be taken with or without a meal.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine during pregnancy and breastfeeding.

If you are pregnant or nursing a baby, taking Ladodin is not recommended.

Driving and using machines

At the recommended dose, Ladodin 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.

Important information about some of the ingredients of Ladodin

Ladodin tablets contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE LADODIN

Adults and adolescents (12 years of age and older): take one tablet once a day.

Swallow the tablet whole with water, with or without food.

Regarding the duration of treatment, your physician will determine the type of allergic rhinitis you are suffering from and will determine for how long you should take Ladodin.

If your allergic rhinitis is intermittent (presence of symptoms for less than 4 days per week or for less than 4 weeks), your physician will recommend you a treatment schedule that will depend on the evaluation of the history of your disease.

If your allergic rhinitis is persistent (presence of symptoms for 4 days or more per week and for more than 4 weeks), your physician may recommend you a longer term treatment.

For urticaria, the duration of treatment may be variable from patient to patient and therefore you should follow the instructions of your physician.

If you take more Ladodin than you should

Take Ladodin only as it is prescribed for you. No serious problems are expected with accidental overdose. However, if you take more Ladodin than you were told to, contact your doctor or pharmacist.

If you forget to take Ladodin

If you forget to take your dose on time, take it as soon as possible, then go back to your regular dosing schedule. Do not take a double dose to make up for a forgotten dose.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Ladodin can cause side effects, although not everybody gets them.

In adults, side effects were about the same as with a dummy tablet. However, the following side effects were reported more often than with a dummy tablet:

- Fatigue
- Dry mouth
- Headache

During the marketing of Ladodin, the following side effects were reported very rarely:

- Severe allergic reactions (difficulty in breathing, wheezing, itching, hives and swelling)
- Rash
- Palpitations
- Rapid heartbeat
- Stomach pain
- Nausea (feeling sick)
- Vomiting
- Upset stomach

- Diarrhoea
- Dizziness
- Drowsiness
- Inability to sleep
- Muscle pain
- Hallucinations
- Seizures
- Restlessness with increased body movement
- Liver inflammation
- Abnormal liver function tests

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE LADODIN

Keep out of reach and sight of children.

Store in the original package in order to protect from light.

Do not use Ladodin after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

Tell your pharmacist if you notice any change in the appearance of the tablets.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Ladodin contains

- The active substance is desloratadine 5 mg
- The other ingredients of the tablet are microcrystalline cellulose (E460), magnesium oxide, pregelatinized starch (maize), lactose anhydrous, hypromellose (E464), zinc stearate, titanium dioxide (E171), macrogol, indigo carmine (aluminium lake E132)

What Ladodin looks like and contents of the pack

Ladodin are blue, round coated tablets.

The tablets are packed in blisters in packs of 10, 20 or 30 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

This medicinal product is authorised in the Member States of the EEA under the following names:

SE : Ladodin

FR : Ladodin

This leaflet was last approved in 2012-04-23