

Package leaflet: information for the patient
Eslorat 5 mg film-coated tablets
desloratadine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Eslorat is and what it is used for
2. What you need to know before you take Eslorat
3. How to take Eslorat
4. Possible side effects
5. How to store Eslorat
6. Contents of the pack and other information

1. What Eslorat is and what it is used for

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

Eslorat tablets 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.

Eslorat tablets is also used to relieve the symptoms associated with urticaria (skin disease 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. What you need to know before you take Eslorat

Do not take Eslorat

- if you are allergic (hypersensitive) to desloratadine or any of the other ingredients of this medicine (listed in section 6) or to loratadine.

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

Warnings and precautions

Consult to your doctor or pharmacist before you start taking Eslorat:

- if you have a decreased renal function
- if you have a medical or family history of seizures

Use in children and adolescents

Do not give this medicine to children less than 12 years of age.



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Taking Eslorat with other medicines

There are no known interactions of Eslorat with other medicines.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Taking Eslorat with food and drinks

Eslorat may be taken with or without a meal.

Use caution when taking desloratadine with alcohol.

Pregnancy, breast-feeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Taking Eslorat is not recommended if you are pregnant or breast-feeding.

Fertility

There is no data available on male/female fertility.

Driving and using machines

At the recommended dose, desloratadine 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 using machines until you have established your own response to the medicinal product.

Eslorat contains lactose

This medicine contains 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 Eslorat

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults and adolescents over 12 years old:

The recommended dose is one tablet once a day with water, with or without food.

This medicine is for oral use.

Swallow the tablet whole.

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

If your allergic rhinitis is intermittent (presence of symptoms for less than 4 days per week or for less than 4 weeks), your doctor 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 doctor may recommend you a long-term treatment.

For urticaria, the duration of treatment may vary from patient to patient and therefore you should follow the instructions of your doctor.

If you take more Eslorat

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

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If too many tablets are taken by accident, contact your doctor or pharmacist at once. Tell them the medicine and the many taken.

If you forget to take Eslorat

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

If you stop taking Eslorat

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

4. Possible adverse effects

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

During the marketing of desloratadine, cases of severe allergic reactions (difficulty in breathing, wheezing, itching, hives and swelling) have been reported very rarely. If you notice any of these serious side effects, stop taking the medicine and seek urgent medical advice straight away.

In clinical studies in adults, side effects were about the same as with a dummy tablet. However, fatigue, dry mouth and headache were reported more often than with a dummy tablet. In adolescents, headache was the most commonly reported side effect.

In clinical studies with desloratadine, the following adverse effects were reported as:

Common : the following may affect up to 1 in 10 people

- fatigue
- dry mouth
- headache

Adults

During the marketing of desloratadine, the following side effects were reported as:

Very rare: the following may affect up to 1 in 10,000 people

- severe allergic reactions
- fast heartbeat
- vomiting
- dizziness
- muscle pain
- restlessness with increased body movement
- skin rash
- stomach ache
- upset stomach
- drowsiness
- hallucinations
- liver inflammation
- pounding or irregular heartbeat
- feeling sick (nausea)
- diarrhoea
- difficulty in sleeping
- seizures
- changes in liver function tests

Not known frequency: frequency cannot be estimated from the available data unusual weakness

- yellowing of the skin and/or eyes

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- increased sensitivity of the skin to the sun, even in case of hazy sun, and to the UV light, for example to UV lights of a solarium
- changes in the way the heart beats
- abnormal behavior
- aggression
- weight increased, increased appetite

Children

Not known frequency: frequency cannot be estimated from the available data

- slow heartbeat
- change in the way the heart beats
- abnormal behavior
- aggression

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Eslorat

Keep this medicine out of the sight and reach of children.

Do not use Eslorat 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.

Store in the original package in order to protect from light and moisture. Store below 30°C. Protect from humidity.

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. Contents of the pack and other information

What Eslorat contains

- The active substance is desloratadine 5 mg
- The other ingredients of the tablet are anhydrous lactose, microcrystalline cellulose, anhydrous hydrogen phosphate calcium, low-substituted hydroxypropyl cellulose, magnesium stearate, anhydrous colloidal silica, hypromellose, titanium dioxide (E-171), talc, indigo carmin lake (E-132) and macrogol 6000.

What Eslorat looks like and contents of the pack

Blue, round, biconvex film-coated tablet and debossed with a "D" on one side. Available in packs of 20 tablets.

Marketing Authorisation Holder and Manufacturer

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