

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Desloratadine Glenmark 5 mg tablets

Read all of this leaflet carefully before you start taking/using 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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Desloratadine Glenmark 5 mg Tablets are and what they are used for
2. What you need to know before you take Desloratadine Glenmark 5 mg Tablets
3. How to take Desloratadine Glenmark 5 mg Tablets
4. Possible side effects
5. How to store Desloratadine Glenmark 5 mg Tablets
6. Contents of the pack and other information

1. What Desloratadine Glenmark 5 mg Tablets are and what they are used for

What Desloratadine 5 mg Tablets is

Desloratadine 5 mg Tablets contain desloratadine which is an antihistamine.

How Desloratadine 5 mg Tablets works

Desloratadine 5 mg Tablets is an antiallergy medicine that does not make you drowsy. It helps control your allergic reaction and its symptoms.

When Desloratadine 5 mg Tablets should be used

- Desloratadine relieves symptoms associated with **allergic rhinitis** (inflammation of the nasal passages caused by an allergy, hay fever or allergy to dust mites) in adults and adolescents 12 years of age and older. These symptoms include sneezing, runny or itchy nose, itchy palate, and itchy, red or watery eyes.
- Desloratadine is also used to relieve symptoms of **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. What you need to know before you take Desloratadine Glenmark 5 mg Tablets

Do not take Desloratadine Glenmark 5 mg Tablets if

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

Warnings – talk to your doctor, pharmacist or nurse

Talk to your doctor, pharmacist or nurse before taking Desloratadine:

- if you have poor kidney function.
- If you have a medical or familial history of seizures.

Use in children and adolescents

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

Other medicines and Desloratadine

There are no known interactions of desloratadine with other medicines.

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

Desloratadine with food, drink and alcohol

Desloratadine Glenmark 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 breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor, or pharmacist for advice before taking this medicine.

Taking Desloratadine is not recommended if you are pregnant or nursing a baby.

Fertility

There is no data available on male/female fertility.

Driving and using machines

At the recommended dose, this medicine 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 medicinal product.

Desloratadine tablets contain lactose

If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before taking this medicinal product.

3. How to take Desloratadine Glenmark 5 mg Tablets

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 aged 12 years of age and over

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 decide for how long you should take Desloratadine Glenmark.

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 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 doctor.

If you take more Desloratadine Glenmark 5 mg Tablets than you should

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

If you forget to take Desloratadine Glenmark 5 mg Tablets

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.

If you stop taking Desloratadine 5 mg Tablets

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

4. Possible side effects

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

During the marketing of Desloratadine 5 mg Tablets, cases of severe allergic reactions (difficulty in breathing, wheezing, itching, hives and swelling of the face, tongue or throat) have been reported very rarely.

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 5 mg Tablets, the following side 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 5 mg Tablets, the following side effects were reported as:

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

- | | | |
|---|----------------------|-----------------------------------|
| ● severe allergic reactions | ● rash | ● pounding or irregular heartbeat |
| ● fast heartbeat | ● stomach ache | ● feeling sick (nausea) |
| ● vomiting | ● upset stomach | ● diarrhoea |
| ● dizziness | ● drowsiness | ● inability to sleep |
| ● muscle pain | ● hallucinations | ● seizures |
| ● restlessness with increased body movement | ● liver inflammation | ● abnormal liver function tests |

Not known: frequency cannot be estimated from the available data

- unusual weakness
- yellowing of the skin and/or eyes
- increased sensitivity of the skin to the sun, even in case of hazy sun, and to UV light, for instance to UV lights of a solarium
- change in the way the heart beats
- abnormal behaviour
- aggression
- weight increased
- increased appetite
- depressed mood
- dry eyes

Children

Not known: frequency cannot be estimated from the available data

- slow heartbeat
- change in the way the heart beats
- abnormal behaviour
- aggression
- depressed mood
- dry eyes

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:

HPRA Pharmacovigilance

Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Desloratadine Glenmark 5 mg Tablets

Keep out of the sight and reach of children.

Do not use this medicine 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.

This medicine does not require any special storage conditions.

Do not use this medicine if you notice any changes in the appearance of the tablets.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information.

What Desloratadine Glenmark 5 mg tablets contain

- The active substance is desloratadine. Each tablet contains 5 mg desloratadine
- The other ingredients of the tablet are Microcrystalline cellulose, Lactose monohydrate, Maize starch, Silica, colloidal anhydrous; Magnesium stearate

What Desloratadine Glenmark 5 mg tablets look like and contents of the pack

Desloratadine tablets are off-white to light-pink, circular, biconvex tablets with 'L5' engraved on one side and plain on the other side.

The tablets are available in blister packs containing 7, 10, 14, 15, 20, 28, 30, 50 or 100 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Glenmark Arzneimittel GmbH
Industriestr.31
Grobenzell
Germany 87194

Manufacturers:

Glenmark Pharmaceuticals s.r.o
Fibichova 143,566 17 Vysoké Mýto,
Czech Republic

This product should be available in the Member States under the following names:

Denmark	Desloratadine Glenmark 5 mg Tabletter
Finland	Desloratadine Glenmark 5 mg tabletit
Germany	Desloratadin Glenmark 5 mg Tabletten
Ireland	Desloratadine Glenmark 5 mg Tablets
Spain	Desloratadina Viso Farmacéutica 5 mg comprimidos EFG
Sweden	Desloratadine Glenmark 5 mg tabletter
The Netherlands	Desloratadine Glenmark 5 mg tabletten

This leaflet was last revised in 10/2023.