PACKAGE LEAFLET

Package leaflet: Information for the patient

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

1. What Desloratadine is and what it is used for

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

Desloratadine is indicated for adults and adolescents (12 years of age and older) to:
relieve 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.

Desloratadine 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.

You must talk to a doctor if you do not feel better or if you feel worse.

2. What you need to know before you take Desloratadine

Do not take Desloratadine:
- if you are allergic to desloratadine, to any of the other ingredients of this medicine (listed in section 6) or to loratadine.

Warnings and precautions
Talk to your doctor or pharmacist before taking Desloratadine if you:

- have medical or familial history of seizures.
- have poor kidney function.

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

Children
Desloratadine tablets are not suitable for children under 12 years of age.

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

Desloratadine with alcohol
Caution is advised when taking desloratadine with alcohol.

Pregnancy and breast-feeding
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.

If you are pregnant or breast-feeding a baby, taking Desloratadine is not recommended.

Driving and using machines
At the recommended dose, Desloratadine 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.

Desloratadine contains Sunset Yellow Aluminium Lake (E110) and Sodium Sunset yellow aluminium lake (E110) may cause allergic reactions.

This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially 'sodium-free'.

3. How to take Desloratadine

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

The recommended dose for adults and adolescents (12 years of age and older) is one tablet once a day. Swallow the tablet whole with water, with or without food.

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 Desloratadine.
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 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, contact your doctor or pharmacist.

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

4. Possible side effects

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

If you notice any of the following side effects, stop taking this medicine and contact your doctor or go to the nearest hospital casualty department straight away:

Very rare: (may affect up to 1 in 10,000 people):

- Severe allergic reactions such as difficulty in breathing, shortness of breath, wheezing, itching, hives and swelling of the face, lips, tongue or other parts of the body and rash
- Fits (seizures)
- Liver disease (nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, light coloured bowel motions, dark coloured urine)

Not known: (frequency cannot be estimated from available data):

- A change in the way the heart beats, which may make you feel dizzy or faint. This may be seen in tests of the electrical activity of the heart ('electrocardiogram' or ECG)

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

Common: (may affect up to 1 in 10 people):

- Fatigue
- Dry mouth
- Headache

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

Very rare: (may affect up to 1 in 10,000 people):

- Fast heartbeat
- Being sick (vomiting)
- Dizziness
- Muscle pain
- Restlessness with increased body movement
- Stomach ache
- Upset stomach
- Drowsiness
- Seeing, feeling or hearing things that are not there (Hallucinations)
- Pounding or irregular heartbeat
- Feeling sick (nausea)
- Diarrhoea
- Inability to sleep
- Abnormal liver function tests

Not known: (frequency cannot be estimated from available data):

- Abnormal behavior
- Aggression
- Unusual weakness
- Increased sensitivity of the skin to the sun, even in the case of hazy sun, and to UV light, for instance to UV lights of a solarium
- Weight increased, increased appetite

- Depressed mood
- Dry eyes

Additional side effects in children and adolescents

Not known: (frequency cannot be estimated from available data):
- Slow heart beat

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Desloratadine

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

This medicine does not require any special storage conditions.

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.

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 protect the environment.

6. Contents of the pack and other information

What Desloratadine contains

The active substance is desloratadine. Each tablet contains 5 mg of desloratadine.
The other ingredients of the tablet are: magnesium stearate, sodium lauril sulfate, silica colloidal anhydrous, microcrystalline cellulose and pregelatinised maize starch.
The tablet film coating contains: poly (vinyl alcohol), indigo carmine aluminium lake (E132), macrogol, talc (E553b) and titanium dioxide (E171). See section 2, 'Desloratadine Mylan contains Sunset Yellow Aluminium Lake (E110) and Sodium'.

What Desloratadine looks like and contents of the pack

Desloratadine are blue, round, tablets with sides that curve outwards marked "DE 5" on one side of the tablet and "M" on the reverse.

Desloratadine 5 mg film-coated tablets are packed in blisters in packs of 2, 3, 5, 7, 10, 15, 20, 30, 50, 60, 90 and 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Mylan, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom

Manufacturers

Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland

Mylan Hungary Ltd., Mylan utca 1., Komárom, 2900, Hungary

This leaflet was last revised in May 2022.