

Package leaflet: Information for the patient**Desloratadine 2.5 mg orodispersible tablets**

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

1. What this medicine is and what it is used for

This medicine contains the active substance desloratadine which is an antihistamine.

This medicine is an anti allergy medicine that does not make you drowsy. It helps control your allergic reaction and its symptoms.

This medicine relieves symptoms associated with allergic rhinitis (inflammation of the nasal passages caused by an allergy, for example, hay fever or allergy to dust mites) in adults, adolescents and children 6 years of age and older. These symptoms include sneezing, runny or itchy nose, itchy palate, and itchy, red or watery eyes.

This medicine 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. What you need to know before you take this medicine**Do not take this medicine**

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

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking this medicine:

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

Use in children and adolescents

Do not give this medicine to children less than 6 years of age.

Taking other medicines

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.

Taking with food, drink and alcohol

This medicine does not need to be taken with water or liquid. Additionally, it 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 this medicine 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.

This medicine contains aspartame

This medicine contains 1.5mg of aspartame in each tablet, which is equivalent to 0.021 mg/kg of body weight in adults and 0.05mg/kg body weight in children.

Aspartame is a source of phenylalanine, which may be harmful for people with phenylketonuria ,a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

Information on sodium content

This medicine contains less than 1mmol sodium (23mg) per tablet, this is to say essentially “sodium free”.

3. How to take this medicine

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 12 years of age and over

The recommended dose is two tablets once a day with or without food.

This medicine is for oral use.

Before using, carefully peel open the blister and remove the dose of orodispersible tablet without crushing it. Place it in your mouth and it will disperse immediately. Water or other liquid is not needed to swallow the dose. Take the dose immediately after removal from the blister.

Children from 6 to 11 years of age

The recommended dose is one tablet once a day 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 this medicine.

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 of this medicine than you should

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



If you forget to take this medicine

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 forgotten individual doses.

If you stop taking this medicine

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, 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 side effects were reported as:

Common: 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: may affect up to 1 in 10,000 people:

- severe allergic reactions
- rash
- pounding or irregular heart beat
- fast heart beat
- stomachache
- 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 (including anger, aggression and agitation)

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 Yellow Card Scheme Website: 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 this medicine

- Keep this medicine 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 medicinal product does not require any special storage conditions
- Do not throw away any medicines via waste water 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 this medicine contains**

- The active substance is desloratadine 2.5mg.
- The other ingredients are polacrillin potassium, citric acid monohydrate, potassium hydroxide, iron oxide red (E172), magnesium stearate, croscarmellose sodium, mannitol (E421), microcrystalline cellulose, aspartame (E951) and flavour Tutti Frutti (consists of flavouring substances, maltodextrin, propylene glycol, modified starch.).

What this medicine looks like and contents of the pack

- These tablets are red-brick, round, flat tablets with beveled edges and ‘2.5’ embossed on one side. The tablet dimensions are 6.4 mm x 2.4 mm.
- This medicine is available in blister packs of 5, 6, 10, 12,15, 18, 20, 30, 50, 60, 90 and 100.
- Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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