

DESLORATADINE 5mg Film-Coated 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 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 Tablets contains the active substance desloratadine which is an antihistamine that does not make you drowsy. It helps control your allergic reaction and its symptoms.

Desloratadine 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 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 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 Desloratadine

Do not take Desloratadine:

- 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 or pharmacist before taking desloratadine:

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

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

May be taken with or without a meal (see

section 3). Use caution when taking desloratadine with alcohol.

Pregnancy, breast-feeding and fertility

The use of desloratadine during pregnancy and breast-feeding is not recommended.

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.

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. However, very rarely some people experience drowsiness, which may affect their ability to concentrate and react. Make sure you are not affected before you drive or operate machinery.

Desloratadine Tablets contain 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 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 doses is:

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

This medicine is for oral use.

Swallow the tablet whole. You can take this medicine with or without food.

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.

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Product:	Desloratadine 5mg Tablets
Item Code:	P2093T
Size:	140 x 230 mm
Min. Point size:	8.5pt
O. Artwork:	25/11/22
Proof No.	1
Amendment Date	

Colours Used	
	Process Black
	Keyline - Does not print

If you take more Desloratadine than you should

Take desloratadine only as it is prescribed for you. No serious problems are expected if you were to accidentally take too many tablets. However, if you take more tablets 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 stop taking Desloratadine

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.

The following side effects have been reported very rarely (may affect up to 1 in 10,000 people):

- severe allergic reactions (difficulty in breathing, wheezing, itching, hives, swelling of the face, mouth or throat) and rash. If you experience any of these symptoms **stop taking** tablets and seek medical attention **IMMEDIATELY**.

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.

Tell your doctor, pharmacist or nurse if you suffer from any of the following other side effects:

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

- fatigue
- dry mouth
- headache.

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

- palpitations (feeling your heartbeat) or rapid heartbeat
- seizures (fits)
- liver inflammation (signs are yellowing of the skin, loss of appetite, stomach discomfort, pale stools and dark urine) and abnormal liver function tests
- hallucinations
- stomach pain, feeling or being sick, indigestion/upset stomach, diarrhoea, vomiting
- dizziness, sleepiness, difficulty in sleeping
- muscle pain
- restlessness with increased body movement.

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

- increased sensitivity of the skin to the sun, even in case of hazy sun and to UV light
- yellowing of the skin and/or the eyes
- abnormal behaviour
- aggression
- changes in the way the heart beats
- feeling of weakness.
- depressed mood

- dry eyes
- Weight increased, increased appetite

Children

(Not known, frequency cannot be estimated from the available data)

- slow heartbeat,
- change in the way heart beats
- abnormal behaviour
- 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 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.

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 store above 30°C. Store in the original package in order to protect from light.

Do not use this medicine if you notice any change 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 protect the environment.

6. Contents of the pack and other information

What Desloratadine Tablets contain

The active substance is desloratadine. Each tablet contains 5mg of desloratadine. The other ingredients are: lactose anhydrous, microcrystalline cellulose, maize starch (partially pregelatinised), magnesium oxide, magnesium stearate and coating containing hypromellose, titanium dioxide (E171), macrogol and indigo carmine aluminium lake (E132).

What Desloratadine Tablets look like and contents of the pack

The film-coated tablets are blue and round.

Desloratadine Tablets are available in pack sizes of 10, 20, 30, 50, 90 or 100 tablets. (Not all pack sizes may be marketed).

Marketing Authorisation Holder and Manufacturer

Crescent Pharma Limited, Units 3 & 4, Quidhampton Business Units, Polhampton Lane, Overton, Hants, RG25 3ED, UK.

This leaflet was last revised in November 2022.

If you would like this leaflet in a different format please contact the marketing authorisation holder at the above address.

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