

Package leaflet: Information for the patient

**DESLORATADINE TABLETS 5 MG
(DESLORASTAL)**

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 any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist. 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 DESLORASTAL are and what they are used for
2. What you need to know before you take DESLORASTAL
3. How to take DESLORASTAL
4. Possible side effects
5. How to store your DESLORASTAL
6. Contents of the pack and other information

1. What DESLORASTAL are and what they are used for

What Desloratadine Tablets are

Desloratadine Tablets contain Desloratadine which is an antihistamine.

How Desloratadine Tablets work

Desloratadine Tablets are an ant allergy medicine that do not make you drowsy. It helps control your allergic reaction and its symptoms.

When Desloratadine Tablets should be used

Desloratadine Tablets relieve 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 Tablets are 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. when your doctor considered this necessary. What you need to know before you take DESLORASTAL Do not take Desloratadine Tablets if:

Do not take Desloratadine:

- if you are allergic to Desloratadine, to any of the other ingredients of this medicine 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 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.

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

5. How to store Desloratadine Tablets

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 Tablets contains

3 X 10 Tablets Alu-Alu Blister Pack

What Desloratadine Tablets looks like and contents of the pack

Blue coloured, Round shaped, biconvex film coated tablet having plain on both side.

3 X 10 Tablets Alu-Alu Blister Pack

DESLORASTAL

Desloratadine Tablets 5mg

Dosage Form:
Oral-Film Coated Tablet

Composition:
Each Film Coated Tablet Contains:
Desloratadine BP 5 mg
Excipients Q.S.
Colour: Brilliant Blue FCF & Titanium Dioxide

Mode of action:
Desloratadine competes with free histamine for binding at H₁-receptors in the GI tract, uterus, large blood vessels, and bronchial smooth muscle. This blocks the action of endogenous histamine, which subsequently leads to temporary relief of the negative symptoms (eg. nasal congestion, watery eyes) brought on by histamine.

Indications:
Seasonal Allergic Rhinitis:
Desloratadine tablet is indicated for the relief of the nasal and non-nasal symptoms of seasonal allergic rhinitis in patients 2 years of age and older.

Perennial Allergic Rhinitis:
Desloratadine tablet is indicated for the relief of the nasal and non-nasal symptoms of perennial allergic rhinitis in patients 6 months of age and older.

Chronic Idiopathic Urticaria:
Desloratadine tablet is indicated for the symptomatic relief of pruritus, reduction in the number of hives, and size of hives, in patients with chronic idiopathic urticaria 6 months of age and older.

Contraindications:
Desloratadine tablet are contraindicated in patients who are hypersensitive to this medication or to any of its ingredients or to loratadine.

Dosage and Administration:
Route of administration: Oral
Adults and children 12 years of age and over:
The recommended dose of Desloratadine tablets is one 5 mg tablet once daily.
Children 6 to 11 years of age:
The recommended dose is one 2.5 mg tablet once daily.
In adult patients with liver or renal impairment, a starting dose of one 5 mg tablet every other day is recommended based on pharmacokinetic data.
Dosing recommendation for children with liver or renal impairment cannot be made due to lack of data.

Adverse reactions:
Common side effects are found: Pharyngitis, dry mouth or throat, somnolence, headache, fatigue, myalgia, nausea, dizziness.
In Children: Fever, diarrhoea, upper respiratory infections, irritability, coughing.

Drug Interactions:
Concomitant use of Desloratadine with inhibitors of the cytochrome P-450 enzyme system, such as Azithromycin, Fluoxetine, Cimetidine, Ketoconazole, Clarithromycin and Erythromycin, may increase the plasma concentration of Desloratadine.

Pregnancy and Lactation:
Pregnancy
The safe use of desloratadine during pregnancy has not been established. Therefore, Desloratadine tablet is not to be used during pregnancy unless clearly indicated.

Lactation
Desloratadine passes into breast milk; therefore a decision should be made whether to discontinue nursing or to discontinue desloratadine, taking into account the importance of the drug to the mother.

Precaution/Warnings:
Desloratadine tablet lacks significant sedative effects, however, some individuals may still experience the sedative effects. Safety and efficacy of Desloratadine tablet in children under 12 years of age have not been established.

Overdose and Treatments:
In the event of overdose, consider standard measures to remove unabsorbed active substance. Symptomatic and supportive treatment is recommended.
Desloratadine is not eliminated by hemodialysis; it is not known if it is eliminated by peritoneal dialysis.

Storage:
Store at a temperature not exceeding 30°C in a dry place. Protect from light. Keep out of reach of children.

Presentation:
3 x 10 Tablets Alu-Alu Blister Pack

Manufactured by:

LABORATORIES PVT. LTD.

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