

DES LoratADINE SANDOZ FILM COATED TABLET

Desloratadine (5mg)

What is in this leaflet:

1. What Desloratadine Sandoz is used for
2. How Desloratadine Sandoz works
3. Before you take Desloratadine Sandoz
4. How to take Desloratadine Sandoz
5. While you are using Desloratadine Sandoz
6. Side effects
7. Storage and disposal of Desloratadine Sandoz
8. Product description
9. Manufacturer & Product Registration Holder
10. Date of revision

What Desloratadine Sandoz is used for

Desloratadine Sandoz relieves symptoms associated with allergic rhinitis (inflammation of the nasal passages caused by an allergy to dust mites). These symptoms include nose, itchy palate, and itchy, red or watery eyes.

Desloratadine Sandoz 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.

How Desloratadine Sandoz works

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

Before you use Desloratadine Sandoz

- When you must not use it

Do NOT take Desloratadine Sandoz

- If you are allergic (hypersensitive) to desloratadine, to any of the other ingredients of Desloratadine Sandoz or to loratadine.

- Before you start to use it

Efficacy and safety of Desloratadine Sandoz in children under 12 years of age have not been established.

Pregnancy and breast-feeding

Pregnancy

Women who are pregnant and intend to become pregnant should consult their doctor before taking Desloratadine Sandoz.

Lactation

It is known that desloratadine appears in human breast milk. If you are breast-feeding, taking Desloratadine Sandoz is not recommended.

- Taking other medicines

There are no known interactions of Desloratadine Sandoz with other medicines.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines.

How to take Desloratadine Sandoz

- How much to take

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

- When to take it

Swallow the tablet whole with water, with or without food.

- How long to take it

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 Desloratadine Sandoz.

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 forget to take Desloratadine Sandoz

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 use too much (overdose)

Contact your doctor or the nearest hospital casualty department immediately. Tell your doctor or pharmacist. There are no known symptoms of overdose.

Take this leaflet or some tablets with you so that people will know what you have taken.

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

While you are using it

- Things you must do

- Take your medicine exactly as your doctor has told you.
- Tell your doctor if you become pregnant while taking this medication.
- If you have any further questions on the use of this product, ask your doctor or pharmacist.

- Things you must not do

- Do not take any new medicines without consulting your doctor.
- Do not give Desloratadine Sandoz to anyone else, even if they have the same symptoms or condition as you.
- Do not stop taking the medicine unless advised by your doctor.

- Things to be careful of

Driving and using machines

At the recommended dose, Desloratadine Sandoz 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.

Side effects

Like all medicines, Desloratadine Sandoz can cause side effects, although not everybody gets them.

Common:

- Headache
- Dry mouth
- Fatigue

Very rare:

- Hallucinations
- Dizziness
- Somnolence
- Insomnia

DES LoratADINE SANDOZ FILM COATED TABLET

Desloratadine (5mg)

- Psychomotor hyperactivity
- Seizures
- Tachycardia
- Palpitations
- Abdominal pain
- Nausea
- Vomiting
- Dyspepsia
- Diarrhea
- Elevations of liver enzymes
- Increased bilirubin
- Hepatitis
- Myalgia
- Hypersensitivity reactions (such as anaphylaxis, angioedema, dyspnoea, pruritus, rash and urticarial)

Frequency unknown:

- Photosensitivity
- QT prolongation, arrhythmia, bradycardia
- Abnormal behaviour
- Aggressive
- Increased appetite
- Increased weight

Stop taking Desloratadine Sandoz and seek medical advice immediately, if you develop any of the allergic reaction signs.

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.

You may report any side effects or adverse drug reactions directly to The National Centre for Adverse Drug Reaction Monitoring by visiting the website nptra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and disposal of Desloratadine Sandoz

- Storage

Store below temperature 30°C. Keep out of the reach and sight of children.

Do not use Desloratadine Sandoz after the expiry date “EXP” which is stated on the packaging.

- Disposal

Medicinal should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Desloratadine Sandoz is a light blue, round shaped, biconvex film coated tablets with “5” debossed on one side.

- Ingredients

Active ingredients

One tablet of Desloratadine Sandoz contains 5 mg desloratadine.

Inactive ingredients

Maize starch, microcrystalline cellulose, hydroxypropyl methylcellulose, purified water, colloidal anhydrous silica, hydrogenated vegetable oil, opadry blue.

MAL Number

MAL17085016AZ

Manufacturer & Product Registration Holder

Manufacturer

Sandoz Private Limited
Plot No.8-A/2 & 8-B,
TTC Industrial Estate,
Kalwe Block, Village-Dighe,
Navi Mumbai - 400 708, India.

Product registration holder

Sandoz Products Malaysia Sdn. Bhd.
3A-2 & 3A-3, Level 3A, Menara KEN
TTDI,
No. 37, Jalan Burhanuddin Helmi,
Taman Tun Dr Ismail,
60000 Kuala Lumpur, Malaysia

Date of revision

Aug 2026

Serial number

NPRA(R2/2)260818/00112