



PATIENT INFORMATION LEAFLET
ALRINAST 5 mg film coated tablet

For oral use
• **Active substance:** Each film-coated tablet contains 5 mg desloratadine.
• **Excipients:** Dibasic calcium phosphate dihydrate, lactose monohydrate, hypromellose, microcrystalline cellulose, corn starch, talc, titanium dioxide, polyethylene glycol, FD&C blue no.2.

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 additional questions, please contact your physician or pharmacist.*
• *This medicine has been prescribed personally for you . Do not give it on to others.*
• *During the use of this drug product, when you visit a physician or go to a hospital, tell your physician that you are using this drug.*
• *Please completely follow the instructions in this information leaflet. Do not use **higher or lower** doses other than what is recommended to you.*

In this leaflet:
1. What is ALRINAST and what is it used for?
2. Before you take ALRINAST
3. How to take ALRINAST?
4. What are the possible side effects?
5. How to store ALRINAST
Titles are included.

1. What is ALRINAST and what is it used for?
ALRINAST contains the active substance desloratadine, which is a class of antihistaminic drugs.
ALRINAST, is an antiallergic medicine that does not make you drowsy. It helps to control allergic reaction and its symptoms.
ALRINAST 5 mg film-coated tablet, light blue coloured, round shaped tablets are available in blister packs containing 20 tablets.
ALRINAST relieves symptoms such as sneezing, runny or itchy nose, itchy palate, and itchy, red or watery eyes associated with allergic rhinitis (inflammation of the nasal passages caused by an allergy, for example, hay fever or allergy to dust mites).
ALRINAST is also used for elimination of symptoms such as elimination of itching with urticaria, swelling and redness of the skin.
These symptoms are resolved throughout the day and helps you to regain your normal daily activities and sleep.

2. Before you take ALRINAST
Alrinast is indicated for adults and adolescents (12 years of age and older).

DO NOT USE ALRINAST:
• If you have hypersensitivity (allergy) to desloratadine, loratadine or any of the other ingredients of this medicine.

Use of ALRINAST with food and beverages
You can take ALRINAST with or without a meal.

Pregnancy
Consult your physician or your pharmacist before using the medicine.
If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine
If, during your treatment, you find out that you are pregnant, immediately consult your physician or your pharmacist.
Taking ALRINAST is not recommended if you are pregnant.

Breast-feeding
Consult your physician or your pharmacist before using the medicine.
Do not take ALRINAST during breast-feeding period.

Seizures
Alrinast should be administered with caution in patients with a medical or family history of seizures. In particular, young children may be more susceptible to developing new seizures under desloratadine treatment. Healthcare providers may consider discontinuing desloratadine in patients who experience a seizure while on treatment.

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 ALRINAST can create drowsiness in some patients and this may affect your driving and using machinery.

Important information about on some of the ingredients found in ALRINAST’s content
This medicinal product contains lactose (milk sugar). If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

Taking other medicines
ALRINAST has no known interactions with other medications.
Please tell your doctor or pharmacist if you are currently taking or have recently taken any other medicines, with or without a prescription.

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

**Instructions for proper use and dose/administration frequency**

Adults and adolescents 12 years of age and over: Take one tablet once a day.
This medicine is for oral use. Swallow the tablet whole with or without a meal and with a glass of water.
Alrinast is not recommended for long term use. Consult a doctor if the condition worsens or does not improve after 14 days.
If you have the impression that effect of ALRINAST is too weak or strong, talk to your physician or pharmacist about it.

If you have used more ALRINAST than necessary:

Take ALRINAST only as it is prescribed for you. No serious problems are expected with accidental overdose.
If you have used more than you should from ALRINAST, talk to a physician or a pharmacist.

If you forget to take ALRINAST

If you forget to take your dose on time, take it immediately as soon as you remember and then go back to your regular dosing schedule.
Do not take double dose to balance out the forgotten dose.

Possible effects when ALRINAST treatment is stopped

There is no reported effect.

4. What are the possible side effects?

Like all medicines, this medicine can cause side effects. The following side effects were reported as:
- Very common; may affect more than 1 in 10 people.
- Common; may affect up to 1 in 10 people.
- Uncommon; may affect up to 1 in 100 people.
- Rare; may affect up to 1 in 1000 people.
- Very rare; may affect up to 1 in 10,000 people
- Not known: Frequency can not be estimated from the available data
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 clinical studies with desloratadine, the following side effects were reported as:

Common:

- Fatigue
- Dry mouth
- Headache

These are the minor side effects of ALRINAST.
The following side effects were reported during the period of Desloratadine film tablet in the market:

Very rare:

- Severe allergic reactions
- Rash
- Restlessness with increased body movement
- Fast heartbeat
- Abnormal liver function tests
- Liver inflammation
- Stomachache
- Nausea (feeling sick)
- Vomiting,
- Diarrhoea
- Inability to sleep
- Drowsiness
- Muscle pain
- Upset stomach
- Hallucinations
- Seizures

Not known:

- 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
- yellowing of the skin and/or eyes
- unusual weakness

If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store ALRINAST?

Store in room temperature below 30°C, protect from moisture.
Store ALRINAST in the package and keep out of the reach and sight of children.

Use in accordance with the expiration date.

Do not use ALRINAST after the expiry date which is stated on the pack. The expiry date refers to the last day of that month.

Do not use ALRINAST if you notice that 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.

Product Registrant:

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Manufacturing Site:

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