

Package leaflet: Information for the patient

Flynise 5 mg Orodispersible Tablets desloratadine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.**
- You must talk to a doctor if you do not feel better or if you feel worse.

What is in this leaflet

1. What Flynise orodispersible tablets are and what they are used for
2. What you need to know before you take Flynise orodispersible tablets
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1. What Flynise orodispersible tablets are and what they are used for

What Flynise is

Flynise contains desloratadine which is an antihistamine.

How Flynise works

Flynise orodispersible tablets are an anti-allergy medicine that does not make you drowsy. They help control your allergic reaction and its symptoms.

When Flynise should be used

Flynise orodispersible 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.

Flynise orodispersible 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.

You must talk to a doctor if you do not feel better or if you feel worse.

2. What you need to know before you take Flynise orodispersible tablets

Do not take Flynise orodispersible tablets

- 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 Flynise:

- if you have poor kidney function.

Use in children and adolescents

Do not give this medicine to children less than 12 years of age.

Other medicines and Flynise

There are no known interactions of Flynise with other medicines.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Flynise orodispersible tablets with food, drink and alcohol

Flynise orodispersible tablets do not need to be taken with water or liquid. Additionally, Flynise orodispersible tablets may be taken with or without a meal. Use caution when taking Flynise 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 Flynise 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.

3. How to take Flynise orodispersible tablets

Always take this medicine exactly as described in this leaflet or 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 one tablet 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.

Regarding the duration of treatment, your doctor or pharmacist will determine the type of allergic rhinitis you are suffering from and will determine for how long you should take Flynise orodispersible tablets. If your allergic rhinitis is intermittent (presence of symptoms for less than 4 days per week or for less than 4 weeks), your doctor or pharmacist 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 or pharmacist 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 or pharmacist.

If you take more Flynise orodispersible tablets than you should

Take Flynise orodispersible tablets only as your doctor or pharmacist has told you. No serious problems are expected with accidental overdose. However, if you take more Flynise orodispersible tablets than you were told to, tell your doctor, pharmacist or nurse immediately.

If you forget to take Flynise orodispersible tablets

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 a forgotten dose.

If you stop taking Flynnise orodispersible tablets

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 trials 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: the following 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: the following may affect up to 1 in 10,000 people

- | | | |
|---|----------------------|-----------------------------------|
| ● severe allergic reactions | ● rash | ● pounding or irregular heartbeat |
| ● fast heartbeat | ● stomach ache | ● 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

Children

Not known: frequency cannot be estimated from the available data

- slow heartbeat
- change in the way the heart beats

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 HPRAs Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Flynnise orodispersible tablets

Keep this medicine out of the sight and reach of children.

Do not store above 25°C.

Store in the original package in order to protect from moisture.

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 use this medicine if you notice any change in the appearance of Flynise orodispersible 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 Flynise orodispersible tablets contain

- The active substance is desloratadine. Each Flynise orodispersible tablet contains 5 mg desloratadine.
- The other ingredients are: *Tablet core*: Microcrystalline cellulose, povidone (K-value 22.5-27), basic butylated methacrylate copolymer, sodium laurilsulfate, dibutyl sebacate, colloidal hydrated silica, dextrans, silicified microcrystalline cellulose (consisting of microcrystalline cellulose and colloidal anhydrous silica), iron oxide red (E172), croscarmellose sodium, sucralose (E955), tutti frutti, magnesium stearate.

What Flynise orodispersible tablets look like and contents of the pack

Flynise 5 mg orodispersible tablets are pink, round, flat tablets with a diameter of approximately 8.0 mm.

[OPA/Adhesive/(OPA/Aluminium/PVC)] / [CC Kraft Paper/PET/Aluminium/HS lacquer] blisters. The blisters are subsequently packed into cardboard boxes.

Pack sizes

Flynise 5 mg orodispersible tablets: 5, 6, 7, 10, 12, 15, 18, 20, 30, 50, 60, 90 and 100 orodispersible tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Actavis Group PTC ehf
Reykjavíkurvegi 76-78
220 Hafnarfjörður
Iceland

Manufacturer

Specifar S.A.
I, 28 Octovriou str., Ag. Varvara,
12351 Athens
Greece

This medicinal product is authorised in the Member States of the EEA under the following names:

Denmark	Flynise
Cyprus	Flynise

Estonia	Flynise
Ireland	Flynise 5 mg Orodispersible Tablets
Hungary	Flynise 5 mg szájban diszpergálódó tableta
Lithuania	Flynise 5 mg burnoje disperguojamosios tabletės
Latvia	Flynise 5 mg mutē disperģejamās tabletes
Malta	Flynise

This leaflet was last revised in June 2015