Package leaflet: Information for the patient

Desloratadine Actavis 5 mg orodispersible tablets
desloratadine

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 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 Desloratadine Actavis is and what it is used for

What Desloratadine Actavis is
Desloratadine Actavis contains desloratadine which is an antihistamine.

How Desloratadine Actavis works
Desloratadine Actavis is an antiallergy medicine that does not make you drowsy. It helps control your allergic reaction and its symptoms.

When Desloratadine Actavis should be used
Desloratadine Actavis 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 Actavis 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 Actavis

Do not take Desloratadine Actavis orodispersible tablets
- if you are allergic to desloratadine, or any of the other ingredients of Desloratadine Actavisthis medicine (listed in section 6) or to loratadine.

Desloratadine ActavisWarnings and precautions
Talk to your doctor, pharmacist or nurse before taking Desloratadine Actavis:
- 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 Desloratadine Actavis
There are no known interactions of Desloratadine Actavis with other medicines.
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Desloratadine Actavis with food, drink and alcohol
Desloratadine Actavis does not need to be taken with water or liquid. Additionally, Desloratadine Actavis may be taken with or without a meal. Use caution when taking Desloratadin Actavis 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 desloratadine 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 Desloratadine Actavis

Always take this medicine exactly 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 physician will determine the type of allergic rhinitis you are suffering from and will determine for how long you should take Desloratadine Actavis. 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 take more Desloratadine Actavis than you should
Take Desloratadine Actavis only as prescribed for you. No serious problems are expected with accidental overdose. However, if you take more Desloratadine Actavis than you were told to, tell your doctor, pharmacist or nurse immediately.

If you forget to take Desloratadine Actavis

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 forgotten individual doses.

If you stop taking Desloratadine Actavis
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, Desloratadine Actavisthis 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 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.

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

During the marketing of desloratadine, the following side effects were reported as:

Very rare: the following may affect up to 1 in10,000 people
- severe allergic reactions
- fast heartbeat
- vomiting
- dizziness
- muscle pain
- restlessness with increased body movement
- rash
- stomach ache
- upset stomach
- drowsiness
- hallucinations
- liver inflammation
- pounding or irregular heartbeat
- feeling sick (nausea)
- diarrhoea
- inability to sleep
- seizures
- 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
The following other side effects were reported in children as:
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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website:www.hpra.ie; E-mail:medsafety@hpra.ie medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Desloratadine Actavis

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 Desloratadine Actavis.

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 Actavis orodispersible tablets contain
- The active substance is desloratadine. Each Desloratadine Actavis 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, dextrates, silicified microcrystalline cellulose, iron oxide red (E172), croscarmellose sodium, sucralose (E955), Tutti frutti, magnesium stearate.

What Desloratadine Actavis orodispersible tablets look like and contents of the pack
Desloratadine Actavis 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
7, 10, 20, 30, 50, 60 and 90 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.
1, 28 Octovriou str., 12351 Ag. Varvara
Athens
Greece

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

Czech Republic	Desloratadine Actavis 2,5 mg Tablety dispergovatelné v ústech
	Desloratadine Actavis 5 mg Tablety dispergovatelné v ústech
Denmark	Desloratadin Actavis Smelte tabletter
Finland	Desloratadine Actavis 2,5 mg tabletti, suussa hajoava
	Desloratadine Actavis 5 mg tabletti, suussa hajoava

Hungary	Desloratadin Actavis 5 mg szájban diszpergálódó tabletta
Ireland	Desloratadine Actavis 5mg Orodispersible Tablets
Portugal	Desloratadina Aurovita

This leaflet was last revised in July 2015