**Package leaflet:**
**Information for the patient**

# Desloratadine Actavis 5 mg film-coated 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:**
- 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 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 may be taken with or without a meal.

Use caution when taking Desloratadine 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 Actavis 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 water, with or without food.

This medicine is for oral use.
Swallow the tablet whole.

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 Actavis.
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 Actavis than you should**
Take Desloratadine Actavis only as it is 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 a forgotten dose.

**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, 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 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

<u>Adults</u>
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

<u>Children</u>
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

**United Kingdom**
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard

**Ireland**
HPRA Pharmacovigilance
Earlsfort Terrace, IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie

**Malta**
ADR Reporting
Website: www.medicinesauthority.gov.mt/adrportal

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 use this medicine after the expiry date which is stated on the carton, bottle label and blister after 'EXP'. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Tell your pharmacist if you notice 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.

## 6. Contents of the pack and other information

**What Desloratadine Actavis contains**
- The active substance is desloratadine. Each film-coated tablet (tablet) contains 5 mg desloratadine.
- The other ingredients are:
  *Tablet core:* Microcrystalline cellulose, starch (pregelatinised), mannitol, talc, magnesium stearate. *Tablet coating:* Hypromellose 6cP, titanium dioxide (E171), macrogol 6000, indigo carmine aluminum lake (E132).

**What Desloratadine Actavis looks like and contents of the pack**
Blue coloured, round, with diameter of 6 mm, biconvex, film-coated tablets with the marking 'LT' engraved on one side.

Desloratadine Actavis 5 mg film-coated tablets are packed in:
Blister packs: 7, 10, 14, 20, 21, 30, 50, 90 or 100 tablets.

Plastic bottles containing a desiccant and closed with a plastic cap: 30 or 100 tablets.
Do not swallow the desiccant.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

*Marketing Authorisation Holder*
Actavis Group PTC ehf.
Reykjavíkurvegi 76-78
220 Hafnarfjörður
Iceland

*Manufacturer*
Actavis Ltd.
BLB 016 Bulebel Industrial Estate
Zejtun ZTN 3000
Malta

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Detailed information on this medicine is available on the European Medicines Agency web site:
http://www.ema.europa.eu

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