Desloratadine Actavis is an antihistamine. Desloratadine Actavis contains desloratadine which is an antiallergy medicine that helps control your allergic reaction and its symptoms.

### How Desloratadine Actavis works
Desloratadine Actavis is an antiallergy medicine that helps control your allergic reaction and its symptoms.

### 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 antihistamine that does not make you drowsy. It helps control your allergic reaction and its symptoms.

### 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.
- if you have medical or familial history of seizures.

**Use in children and adolescents**
Do not give this medicine to children less than 12 years of age.

### 3. How to take Desloratadine Actavis

**Adults**
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.
- if you have medical or familial history of seizures.

**Use in children and adolescents**
Do not give this medicine to children less than 12 years of age.

### 4. Possible side effects

- **Common**:
  - the following may affect up to 1 in 10 people
    - unusual weakness
    - yellowing of the skin and/or eyes
    - increased sensitivity of the skin to the sun
    - increased sensitivity to UV lights of a solarium
    - changes in the way the heart beats
    - abnormalities in blood pressure

- **Unlikely**:
  - the following may affect less than 1 in 10 people
    - sweating
    - skin rash
    - difficulty in swallowing

- **Rare**:
  - the following may affect less than 1 in 1000 people
    - breathing difficulties
    - high blood pressure
    - increased blood sugar levels

- **Very rare**:
  - the following may affect less than 1 in 100,000 people
    - heart rhythm disturbances
    - blood vessel problems
    - changes in the way the heart beats

**Reduction of side effects**
- Take Desloratadine Actavis only as it is prescribed by your doctor, pharmacist or nurse.
- Do not take more Desloratadine Actavis than you need.
- If you take more Desloratadine Actavis than you need, talk to your doctor, pharmacist or nurse immediately.

**Driving and using machines**
Patients should use caution when taking Desloratadine Actavis with other medicines. There are no known interactions of Desloratadine Actavis with other medicines.

**Other medicines and Desloratadine Actavis**
There are no known interactions of Desloratadine Actavis with other medicines.

**Use in children and adolescents**
Do not give this medicine to children less than 12 years of age.

**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 with 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

**Side effects not listed in this leaflet. See section 4.**

**In case of hazy sun, and to UV light, for instance a tanning bed or sunbed, use protective measures such as chemical UV filters, protective clothing, protective cream or lotions.**
Children
Not known: frequency cannot be estimated from the available data
• slow heartbeat
• change in the way the heart beats
• abnormal behaviour
• aggression

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

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

United Kingdom
Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store
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 60K, titanium dioxide (E171), macrogl 6000, indigo carmine aluminium 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

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

Ireland
Actavis Ireland Limited
Tel: +353 (0)21 4619040

United Kingdom
Actavis UK Limited
Tel: +44 1271 385257

This leaflet was last revised in November 2017
Detailed information on this medicine is available on the European Medicines Agency web site:
http://www.ema.europa.eu

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