

Package leaflet: Information for the patient

Desloratadine Cipla 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 or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
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- If you get any side effect talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

1. What Desloratadine Cipla is and what it is used for
2. What you need to know before you take Desloratadine Cipla
3. How to take Desloratadine Cipla
4. Possible side effects
5. How to store Desloratadine Cipla
6. Contents of the pack and other information

1. What Desloratadine cipla is and what it is used for

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

Desloratadine relieves symptoms associated with allergic rhinitis (inflammation of the nasal passages caused by an allergy, for example, *hay fever* or allergy to dust *mites*). These symptoms include sneezing, runny or itchy nose, itchy palate, and itchy, red or watery eyes.

Desloratadine Cipla 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 Cipla

Do not take Desloratadine Cipla

- if you are allergic to desloratadine, or any of the other ingredients of Desloratadine Cipla or to loratadine (listed in section 6)

Warnings and precautions

Talk to your doctor or pharmacist before taking Desloratadine Cipla

- if you have poor kidney function.
- Children and adolescents
Desloratadine Cipla is indicated in adults and adolescents (12 years of age and older).

Other medicines and Desloratadine Cipla

There are no known interactions of Desloratadine Cipla with other medicines.

Desloratadine Cipla with food and drink

Desloratadine Cipla may be taken with or without a meal.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine during pregnancy and breast-feeding.

If you are pregnant or nursing a baby, taking Desloratadine Cipla is not recommended.

Driving and using machines

At the recommended dose, Desloratadine Cipla is not expected to cause you to be drowsy or less alert. However very rarely some people experience drowsiness, which may affect their ability to drive or use machines.

3. How to take Desloratadine Cipla

Adults and adolescents (12 years of age and older): take one tablet once a day.

Swallow the tablets whole with water, with or without food.

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 Cipla.

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 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 Cipla than you should

Take Desloratadine Cipla only as it is prescribed to you. No serious problems are expected with accidental overdose. However, if you take more than you were told to, contact your doctor or pharmacist.

If you forget to take Desloratadine Cipla

If you forget to take your dose on time, take it as soon as possible, then go back to your regular dosing schedule. Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

Like all medicines, Desloratadine Cipla can cause side effects, although not everybody gets them.

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.

During the marketing of Desloratadine Cipla, cases of severe allergic reactions (difficulty in breathing, wheezing, itching, hives and swelling) and rash have been reported very rarely. Cases of palpitations, rapid heartbeat, stomach pain, nausea (feeling sick), vomiting, upset stomach, diarrhoea, dizziness, drowsiness, inability to sleep, muscle pain, hallucinations, seizures, restlessness with increased body movement, liver inflammation and abnormal liver function tests have also been reported very rarely.

If any of the side effects gets serious, or if you notice any side effects not listed in this in this leaflet, please tell your doctor or pharmacist.

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom: Yellow Card Scheme at: 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 at: www.medicinesauthority.gov.mt/adrportal

5. How to store Desloratadine Cipla:

Store below 25⁰C. Store in the original package in order to protect from light. Keep out of the sight and reach of children.

Do not use Desloratadine Cipla after the expiry date which is stated on the carton after Exp.

The expiry date refers to the last day of that month.

Tell your pharmacist if you notice any change in the appearance of the tablets.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Desloratdine Cipla contains

The active substance is desloratadine 5 mg

The other ingredients are mannitol, low-substituted hydroxyl propyl cellulose, castor oil hydrogenated, silica colloidal anhydrous, talc, simethicone, hypromellose 15 cp, titanium dioxide (E171), macrogol, indigo carmine aluminium lake (E132)

What Desloratadine Cipla looks like and contents of the pack

Light blue coloured, circular, biconvex, film-coated tablet with diameter of 7.00 mm plain on both sides.

Carton containing blister (PVC/ACLAR film and plain aluminium foil) of 5 ,10 ,20, 30 , 50 and 100 tablets each.

Not all pack sizes may be marketed.

Marketing authorization holder

Cipla Europe NV
Uitbreidingstraat 80
2600 Antwerp
Belgium

Manufacturer

S & D Pharma, CZ, spol. s.r.o.

Registered office of the company:

Písnická 22/546, 142 00 Prague 4,

Czech Republic, IČ:25087193

Place of manufacture:

Theodor 28, 273 08 Pchery (PHARMOS a.s. facility),

Czech Republic

Cipla (EU) Limited,
20 Balderton Street, London W1K 6TL United Kingdom

Cipla Europe NV
Uitbreidingstraat 80
2600 Antwerp
Belgium

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

Sweden - Desloratadine Cipla 5 mg filmdragerade tabletter
Bulgaria - Деслоратадин Сипла 5 mg филмирани таблетки
Czech Republic – DELESIT 5 mg potahované tablety
Slovak Republic – DELESIT 5 mg filmom obalené tablety
Hungary- Desloratadine Cipla 5 mg filmtabletta
Belgium: Desloratadine Cipla 5 mg comprimés pelliculés
Cyprus: Desloratadine Cipla 5 mg επικαλυμμένα με λεπτό υμένιο δισκία
Germany: Desloratadin Cipla 5 mg Filmtabletten
Denmark: Desloratadin Cipla
Greece: Desloratadine Cipla 5 mg επικαλυμμένα με λεπτό υμένιο δισκία
Spain: Desloratadine Cipla 5 mg comprimidos recubiertos con película
Croatia: Desloratadin Cipla 5 mg filmom obložene tablete
Ireland: Desloratadine Cipla 5 mg film-coated tablets
Italy: Desloratadina Cipla
Malta: Desloratadine Cipla 5 mg film-coated tablets
Norway: Desloratadine Cipla 5 mg tabletter, filmdrasjerte
Poland: Desloratadine Cipla
Portugal: Desloratadina Cipla 5 mg comprimidos revestidos por película
Romania: Desloratadina Cipla 5 mg comprimate filmate
Slovenia: Desloratadin Cipla 5 mg filmsko obložene tablete
United Kingdom: Desloratadine Cipla 5 mg film-coated tablets

This leaflet was last updated in 05/2016