

Package leaflet: Information for the patient

Dasergin 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 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Dasergin is and what it is used for

What Dasergin is

Dasergin contains desloratadine which is an antihistamine.

How Dasergin works

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

When Dasergin should be used

Dasergin 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.

Dasergin 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 Dasergin

Do not take Dasergin

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Dasergin:

- if you have poor kidney function.
- if you have medical or familial history of seizures.

Children and adolescents

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

Other medicines and Dasergin

There are no known interactions of Dasergin with other medicines. Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Dasergin with food, drink and alcohol

Dasergin may be taken with or without a meal.

Use caution when taking Dasergin 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.

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

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.

Dasergin contains lactose and sodium

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Dasergin

Always take this medicine exactly as described in this leaflet.

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 or pharmacist will determine the type of allergic rhinitis you are suffering from and will determine for how long you should take Dasergin.

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 Dasergin than you should

Take Dasergin only as described in this leaflet. No serious side effects are expected with accidental overdose. However, if you take more Dasergin than you were told to, tell your doctor or pharmacist immediately.

If you forget to take Dasergin

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 tablet.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

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 (may affect up to 1 in 10 people):

- fatigue,
- dry mouth,
- headache.

Adults

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

Very rare (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,
- changes in the way the heart beats,
- abnormal behaviour,
- aggression,
- increased appetite,
- weight increased.

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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in

HPRA 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 Dasergin

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 packaging (box and blister) after EXP. The expiry date refers to the last day of that month.

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

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 Dasergin contains

- The active substance is desloratadine. Each film-coated tablet contains 5 mg desloratadine.
- The other ingredients are: microcrystalline cellulose, hypromellose, hydrochloric acid (for pH-adjustment), sodium hydroxide (for pH-adjustment), maize starch, lactose monohydrate and talc in the tablet core and hypromellose, macrogol 400, lactose monohydrate, titanium dioxide (E171) and indigo carmine (E132) in the film-coating. See section 2 »Dasergin contains lactose and sodium«.

What Dasergin looks like and contents of the pack

Light blue, round, film-coated tablets (tablets) with beveled edges (diameter: 6.5 mm, thickness: 2.3–3.5 mm).

Dasergin is available in boxes of 10, 30 or 100 film-coated tablets in blisters.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

HCS bvba, H Kennisstraat 53, B 2650 Edegem, Belgium

Manufacturer

KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

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

Name of the Member State	Name of the medicinal product
Belgium, France	Desloratadine HCS
Spain	Desloratadina HCS
Ireland	Dasergin

This leaflet was last revised in

