

Package leaflet: Information for the patient

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

1. What Efestad is and what it is used for

What Efestad is

Efestad contains desloratadine which is an antihistamine.

How Efestad works

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

When Efestad should be used

Efestad 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.

Efestad 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 Efestad

DO NOT take Efestad

- 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 or pharmacist before taking Efestad

- 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.

Other medicines and Efestad

There are no known interactions of Efestad with other medicines.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Efestad with food, drink and alcohol

Efestad may be taken with or without a meal.

Use caution when taking Efestad 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 Efestad 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.

Efestad contains isomalt

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

3. How to take Efestad

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.

Method of administration

This medicine is for oral use.

Swallow the tablet whole.

Duration of treatment

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 Efestad. 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 Efestad than you should

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

If you forget to take Efestad

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 Efestad

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 Efestadcan 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

Adults

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

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|---|----------------------|-----------------------------------|
| • 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
- abnormal behaviour
- aggression
- weight increased, increased appetite

Children

Not known: frequency cannot be estimated from the available data

- slow heart beat
- change in the way the heart beats
- abnormal behaviour
- aggression
- weight increased, increased appetite

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. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Efestad

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

Do not store above 30°C.

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

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 Efestad contains

The active substance is desloratadine. Each tablet contains 5 mg desloratadine.

The other ingredients are:

Tablet core:

Isomalt (E953)
Starch, Pregelatinized (Maize)
Cellulose, Microcrystalline
Magnesium oxide, heavy
Hydroxypropylcellulose
Crospovidone (type A)
Magnesium stearate.

Tablet coating:

Polyvinyl Alcohol
Titanium Dioxide (E171)
Macrogol / PEG 3350
Talc
FD&C Blue #2 / Indigo carmine
Aluminium Lake (E132).

What Efestad looks like and contents of the pack

Efestad 5 mg film-coated tablets are blue, round, biconvex film coated tablets with a diameter of approximately 6.5 mm.

Efestad 5 mg film-coated tablets are packed in Polychlorotrifluoroethylene (PCTFE)/Polyvinyl Chloride (PVC) / Aluminium blisters.

Efestad 5 mg film-coated tablets are packed in unit dose blisters in packs of 7, 10, 20, 30 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

Manufacturer:

Specifar S.A., 1, 28 Octovriou str., Ag. Varvara, 12351 Athens, Greece

STADA Arzneimittel AG, Stadastrasse 2–18, 61118 Bad Vilbel, Germany

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

BG Efestad 5 mg filmcoated tablets

DK Valora

IE Efestad 5 mg film-coated tablets

IT EFESTAD 5 mg compresse rivestite con film

This leaflet was last revised in November 2017.