

PACKAGE LEAFLET: INFORMATION FOR THE USER

DES-FLONIDAN

5 mg film-coated tablets

DESLORATADINE

• *This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •*

What is in this leaflet?

1. What Des-Flonidan is and what it is used for
2. What you need to know before you take Des-Flonidan
3. How to take Des-Flonidan
4. Possible side effects
5. How to store Des-Flonidan

1. WHAT DES-FLONIDAN IS AND WHAT IT IS USED FOR

What Des-Flonidan is

Des-Flonidan contains desloratadine which is an antihistamine.

How Des-Flonidan works

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

When Des-Flonidan should be used

Des-Flonidan 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.

Des-Flonidan 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 DES-FLONIDAN

Do not take Des-Flonidan

- if you are allergic to desloratadine, or any of the other ingredients of this medicine or to loratadine.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Des-Flonidan:

- 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 Des-Flonidan

There are no known interactions of Des-Flonidan with other medicines.

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

Des-Flonidan with food, drink and alcohol

Des-Flonidan may be taken with or without a meal.

Use caution when taking Des-Flonidan 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 Des-Flonidan 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.

Des-Flonidan contains lactose

Des-Flonidan tablets contain lactose. 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 DES-FLONIDAN

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 physician will determine the type of allergic rhinitis you are suffering from and will determine for how long you should take Des-Flonidan.

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 Des-Flonidan than you should

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

If you forget to take Des-Flonidan

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 Des-Flonidan

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 Des-Flonidan, 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 Des-Flonidan, 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 Des-Flonidan, the following side effects were reported as:

Very rare: the following may affect up to 1 in 10,000 people

- severe allergic reactions
- fast heartbeat
- vomiting
- dizziness
- muscle pain
- restlessness with increased body movement
- rash
- stomach ache
- upset stomach
- drowsiness
- hallucinations
- liver inflammation
- pounding or irregular heartbeat
- feeling sick (nausea)
- diarrhoea
- inability to sleep
- seizures
- abnormal liver function tests

Not known: frequency cannot be estimated from the available data

- unusual weakness
- 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
- yellowing of the skin and/or eyes

Children

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.

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

5. HOW TO STORE DES-FLONIDAN

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.

Do not use this medicine 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 to protect the environment.

This leaflet was last revised in February 2015