Package leaflet: Information for the patient

Desloratadine Clonmel 0.5 mg/ml Oral Solution

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 Desloratadine Clonmel is and what it is used for

What Desloratadine Clonmel is
Desloratadine Clonmel contains desloratadine which is an antihistamine.

How Desloratadine Clonmel works
Desloratadine Clonmel oral solution is an antiallergy medicine that does not make you drowsy. It helps control your allergic reaction and its symptoms.

When Desloratadine Clonmel should be used
Desloratadine Clonmel oral solution 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, adolescents and children 1 year of age and older. These symptoms include sneezing, runny or itchy nose, itchy palate, and itchy, red or watery eyes.

Desloratadine Clonmel oral solution 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 Clonmel

DO NOT take Desloratadine Clonmel
- if you are allergic to desloratadine, or to any of the other ingredients of this medicine (listed in section 6) or to loratadine.Desloratadine Clonmel

Warnings and precautions
Talk to your doctor or pharmacist before taking Desloratadine Clonmel
- 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 1 year of age.

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

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

Desloratadine Clonmel with food, drink and alcohol
Desloratadine Clonmel may be taken with or without a meal.
Use caution when taking Desloratadine Clonmel 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 Desloratadine Clonmel oral solution 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.

Desloratadine Clonmel contains sorbitol
Desloratadine Clonmel oral solution contains sorbitol. 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 Desloratadine Clonmel
Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Children
Children 1 through 5 years of age:
The recommended dose is 2.5 ml (½ of a 5 ml spoonful) of oral solution once a day.

Children 6 through 11 years of age:
The recommended dose is 5 ml (one 5 ml spoonful) of oral solution once a day.

Adults and adolescents 12 years of age and over
The recommended dose is 10 ml (two 5 ml spoonfuls) of oral solution once a day.

In case an oral measuring syringe is provided with the bottle of oral solution, you can alternatively use it to take the appropriate amount of oral solution.

Method of administration
This medicine is for oral use.

Swallow the dose of oral solution and then drink some water. You can take this medicine with or without food.

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

If you forget to take Desloratadine Clonmel
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 Desloratadine Clonmel
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 most children and adults, side effects with desloratadine were about the same as with a dummy solution or tablet. However, common side effects in children less than 2 years of age were diarrhoea, fever and insomnia while in adults, fatigue, dry mouth and headache were reported more often than with a dummy tablet.

In clinical studies with desloratadine, the following side effects were reported as:

Children
Common in children less than 2 years of age: the following may affect up to 1 in 10 children
- diarrhoea
- fever
- insomnia

Adults
Common: the following may affect up to 1 in 10 people
- fatigue
- dry mouth
- headache

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

Adults
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
- 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

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 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 Desloratadine Clonmel
Keep this medicine out of the sight and reach of children.

Do not use Desloratadine Clonmelthis medicine after the expiry date which is stated on the bottle after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

After first opening the solution should be used within 2 months.

Do not use this medicine if you notice any change in the appearance of the oral solution.

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 Clonmel contains
The active substance is desloratadine. Each ml of Desloratadine Clonmel contains 0.5 mg desloratadine.
The other ingredients of the oral solution are:
Sorbitol liquid (E420) (non-crystallizing)
Propylene glycol
Citric acid monohydrate
Sodium citrate
Hypromellose 2910
Sucralose
Disodium edetate
Tutti frutti
Purified water.

What Desloratadine Clonmel looks like and contents of the pack
Desloratadine Clonmel oral solution is presented as a clear colourless solution, free from foreign matters. Desloratadine Clonmel oral solution is supplied in two different volume sizes 100 and 120 ml and packaged in Type III amber glass bottles closed with either a plastic child resistant (C/R) screw closure having a multi-ply polyethylene-faced liner, or a plastic child resistant (C/R) screw closure consisting of an outer and an inner layer of polypropylene and polyethylene respectively. The bottles are subsequently packed into cardboard boxes. All packages are supplied with a measuring spoon marked for doses of 2.5 ml and 5 ml or an oral measuring syringe of a final volume of 5 ml marked on every 0.5 ml.

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
Famar Orleans, 5 avenue de Concyr, 45071 Orleans CEDEX 2, France

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

Bulgaria	Desloratadine Stada 0.5 mg/ml oral solution
Denmark	Desloratadin Stada Arzneimittel
Ireland	Desloratadine Clonmel 0.5 mg/ml oral solution

This leaflet was last revised in May 2017.