

## **Package leaflet: Information for the patient**

### **Desloratadine Denk 0,5 mg/ml drank** 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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

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

#### **1. What Desloratadine Denk is and what it is used for**

##### **What Desloratadine Denk is**

Desloratadine Denk contains desloratadine which is an antihistamine

##### **How Desloratadine Denk works**

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

##### **When Desloratadine Denk should be used**

Desloratadine Denk 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 Denk 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 Denk**

##### **Do not take Desloratadine Denk**

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

#### **Warnings and precautions**

Talk to your doctor, pharmacist or nurse before taking Desloratadine Denk

- 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 1 year of age.

### **Other medicines and Desloratadine Denk**

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

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

### **Desloratadine Denk oral solution with food, drink and alcohol**

Desloratadine Denk may be taken with or without a meal.

Use caution when taking Desloratadine Denk 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 Denk 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 Denk oral solution contains sorbitol**

Desloratadine Denk oral solution contains 150 mg of sorbitol in each ml.

Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars, or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

### **Desloratadine Denk oral solution contains propylene glycol**

Desloratadine Denk oral solution contains 150.51 mg propylene glycol in each ml.

## **3. How to take Desloratadine Denk oral solution**

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 (1/2 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.

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.

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 Denk 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 Denk oral solution than you should**

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

**If you forget to take Desloratadine Denk oral solution**

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 Denk oral solution**

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 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
- 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
- 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
- weight increased, increased appetite
- yellowing of the skin and/or eyes
- depressed mood
- dry eyes

#### Children

Not known: frequency cannot be estimated from the available data

- slow heartbeat
- abnormal behaviour
- aggression
- change in the way the heart beats

## **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 Nederlands Bijwerkingen Centrum Lareb, website: [www.lareb.nl](http://www.lareb.nl). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Desloratadine Denk oral solution**

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

This medicinal product does not require any special storage conditions. Store in the original package in order to protect from light.

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. 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 Denk contains**

The active substance is desloratadine 0.5 mg/ml.

The other ingredients are sodium citrate, sorbitol (E420), sucralose, citric acid, propylene glycol (E1520), hypromellose, tutti-frutti flavour and purified water.

### **What Desloratadine Denk looks like and contents of the pack**

Desloratadine Denk oral solution is available in bottles with a childproof cap.

Packages of 30 ml, 50 ml, 60 ml, 100 ml, 120 ml and 150 ml are supplied with a measuring spoon or a measuring syringe. Packages of 225 ml and 300 ml are supplied with a measuring spoon.

The measuring syringe is multiply graduated to supply doses of 2.5 and 5 ml.

The measuring spoon has capacities of 2.5 and 5 ml.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder**

Denk Pharma GmbH & Co. KG  
Prinzregentenstraße 79  
81675 München  
Duitsland

### **Manufacturer**

Geneparm S.A.  
18 km Marathonos Avenue  
153 51 Pallini Attiki  
Griekenland

Famar A.V.E.  
49th km National road Athens-Lamia  
Avlona Attiki, 19011  
Griekenland

**In het register ingeschreven onder:**

RVG 124513

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

Nederland: Desloratadine Denk 0,5 mg/ml drank  
Duitsland: Desloratadin Denk 0,5 mg/ml Lösung zum Einnehmen

**Deze bijsluiter is voor het laatst goedgekeurd in mei 2022.**