

Package leaflet: Information for the patient

Neoclarityn® 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, 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

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2. What you need to know before you take Neoclarityn oral solution
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1. What Neoclarityn oral solution is and what it is used for

What Neoclarityn is

Neoclarityn contains desloratadine which is an antihistamine.

How Neoclarityn works

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

When Neoclarityn should be used

Neoclarityn 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.

Neoclarityn 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 Neoclarityn oral solution

Do not take Neoclarityn oral solution

- 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 Neoclarityn:

- 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 Neoclarityn

There are no known interactions of Neoclarityn with other medicines.

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

Neoclarityn oral solution with food, drink and alcohol

Neoclarityn may be taken with or without a meal.

Use caution when taking Neoclarityn 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 Neoclarityn 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.

Neoclarityn oral solution contains sorbitol

Neoclarityn 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 Neoclarityn 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 ($\frac{1}{2}$ 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 Neoclarityn 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 Neoclarityn oral solution than you should

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

If you forget to take Neoclarityn 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 Neoclarityn 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 Neoclarityn, 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 Neoclarityn 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 Neoclarityn, 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 Neoclarityn, 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
- restlessness with increased body movement
- hallucinations
- liver inflammation
- 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
- changes in the way the heart beats
- abnormal behaviour
- aggression
- weight increased, increased appetite
- yellowing of the skin and/or eyes

Children

Not known: frequency cannot be estimated from the available data

- slow heartbeat
- abnormal behaviour
- change in the way the heart beats
- 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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom: Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

Ireland: HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie

Malta: ADR Reporting at: www.medicinesauthority.gov.mt/adrportal

5. How to store Neoclarityn 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 bottle after EXP. The expiry date refers to the last day of that month.

Do not freeze. Store in the original package.

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 to protect the environment.

6. Contents of the pack and other information

What Neoclarityn oral solution contains

- The active substance is desloratadine 0.5 mg/ml
- The other ingredients of the oral solution are sorbitol, propylene glycol, sucralose E 955, hypromellose 2910, sodium citrate dihydrate, natural and artificial flavour (bubblegum), citric acid anhydrous, disodium edetate and purified water.

What Neoclarityn oral solution looks like and contents of the pack

Neoclarityn oral solution is available in bottles of 30, 50, 60, 100, 120, 150, 225 and 300 ml, with a childproof cap. For all packages except the 150 ml bottle, a measuring spoon is provided, marked for doses of 2.5 ml and 5 ml. For the 150 ml package, a measuring spoon or an oral measuring syringe is provided, marked for doses of 2.5 ml and 5 ml.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Merck Sharp & Dohme B.V.
Waarderweg 39
2031 BN Haarlem
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Manufacturer: SP Labo N.V., Industriepark 30, B-2220 Heist-op-den-Berg, Belgium.

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder:

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Detailed information on this medicine is available on the European Medicines Agency website
<http://www.ema.europa.eu>.

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