# PATIENT INFORMATION LEAFLET

**SCHEDULING STATUS:** S2

**NEOLORIDIN 2,5** tablet

2,5 mg desloratadine

Contains sweetener: 10 mg aspartame per tablet.

Contains sugar alcohol: 55,5 mg mannitol per tablet.

**NEOLORIDIN 5** tablet

5 mg desloratadine

Contains sweetener: 10 mg aspartame per tablet.

Contains sugar alcohol: 52,5 mg mannitol per tablet.

**Read all of this leaflet carefully because it contains important information for you.**

NEOLORIDIN is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to take NEOLORIDIN carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share NEOLORIDIN with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

**What is in this leaflet**

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

## 1. What NEOLORIDIN is and what it is used for

NEOLORIDIN is an antihistamine indicated for the relief of symptoms associated with:

- Seasonal allergic rhinitis (an allergic condition with symptoms of sneezing, a runny nose and itching of the eyes, nose and throat).
- Chronic idiopathic urticaria (a skin condition caused by an allergy with symptoms such as itching and hives) (short-term relief).

## 2. What you need to know before you take NEOLORIDIN

### Do not take NEOLORIDIN

- If you are hypersensitive (allergic) to desloratadine or any of the other ingredients of NEOLORIDIN (listed in section 6).
- If you are sensitive or allergic to other antihistamines (used to treat allergies).
- If you are pregnant or breastfeeding your baby (see “Pregnancy and breastfeeding”).
- If you are suffering from porphyria (a rare blood disorder).

### Warnings and precautions

Take special care with NEOLORIDIN:

- If you are suffering from liver function impairment.
- If you have kidney problems.
- If you are an elderly patient and are more likely to have age-related impairment of the liver or kidney function, which may require adjustment of your dose of NEOLORIDIN.
- If you must go for a skin test with allergen extracts, stop taking NEOLORIDIN at least 48 hours before the test.
- If you suffer from emphysema (a condition in which the air sacs of your lungs are damaged and enlarged, causing breathlessness).
- If you have an enlarged prostate.
- If you have narrow angle glaucoma (an eye condition with symptoms such as severe pain, blurry vision, redness and nausea).
- If you have a heart or circulation disorder.

- If you suffer from epilepsy.
- If you suffer from asthma. Do not take NEOLORIDIN during acute asthma attacks.
- If you have a medical or familial history of seizures.

***Children and adolescents***

Safety of NEOLORIDIN in children under two years of age has not been established.

**Other medicines and NEOLORIDIN**

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

Tell your doctor or pharmacist if you are currently using:

- Cimetidine (used to treat heartburn).
- Ketoconazole (used to treat fungal infections).
- Clarithromycin, erythromycin (used to treat bacterial infections).
- Fluoxetine (used to treat depression).

**Taking NEOLORIDIN with food, drink and alcohol**

NEOLORIDIN can be taken with or without food.

Caution should be taken if alcohol is taken simultaneously.

**Pregnancy, breastfeeding and fertility**

If you are pregnant or breastfeeding your baby, think you may be pregnant or planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking NEOLORIDIN.

Do not take NEOLORIDIN if you are pregnant or breastfeeding.

**Driving and using machines**

NEOLORIDIN may cause drowsiness and can affect your ability to drive a vehicle and use

machines (see Possible side effects). Do not drive a vehicle, operate machinery, or do anything else that requires your attention until you know how NEOLORIDIN affects you.

**NEOLORIDIN contains aspartame and mannitol:**

Aspartame is a source of phenylalanine. If you have an inherited illness called phenylketonuria, consult your doctor before taking NEOLORIDIN.

Mannitol may have a mild laxative effect.

## 3. How to take NEOLORIDIN

Always take NEOLORIDIN exactly as described in this leaflet or as instructed by your doctor or pharmacist. You should check with your doctor or pharmacist if you are unsure.

**NEOLORIDIN 2,5**

***Children 2 to 5 years of age:***

Half a tablet once a day, with or without a meal.

***Children 6 to 11 years of age:***

One tablet (2,5 mg) once a day, with or without a meal.

***Adults and adolescents (≥ 12 years):***

Two tablets (2,5 mg) once a day, with or without a meal.

**NEOLORIDIN 5**

***Adults (≥ 12 years of age):***

One tablet (5 mg) orally, once daily, with or without a meal.

If you have the impression that the effect of NEOLORIDIN is too strong or too weak, tell your doctor or pharmacist.

**If you take more NEOLORIDIN than you should:**

In the event of an overdosage, consult your doctor or pharmacist. If neither is available, contact the

nearest hospital or poison centre. Take this leaflet and the remaining NEOLORIDIN tablets with you so the doctor will know what you have taken.

**If you forget to take NEOLORIDIN:**

If you have missed your dose by only a few hours, take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take NEOLORIDIN at the next regularly scheduled time.

Do not take a double or larger dose of NEOLORIDIN to make up for the forgotten individual doses.

If you have trouble remembering when to use NEOLORIDIN, ask your pharmacist for some hints.

## 4. Possible side effects

NEOLORIDIN can have side effects.

Not all side effects reported for NEOLORIDIN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking NEOLORIDIN, please consult your healthcare provider for advice.

If any of the following happens, stop taking NEOLORIDIN and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to NEOLORIDIN. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

*Less frequent:*

- Fast, pounding or irregular heartbeat or pulse.

- Seizures (fits).

*Frequency unknown:*

- Yellowing of the skin and eyes, also called jaundice.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor as soon as possible if you notice any of the following:

*Frequent:*

- Headache.
- Dry mouth.
- Unusual tiredness or weakness (fatigue).

*Less frequent:*

- Dizziness.
- Stomach pain, nausea (feeling sick), vomiting (being sick), indigestion (acid or sour stomach), diarrhoea.
- Muscle aches or cramps.
- Sleepiness or inability to sleep, drowsiness.
- Hallucinations (seeing or hearing things that do not exist).
- Restlessness with increased body movement.
- Liver inflammation, abnormal liver function tests.

*Frequency unknown:*

- Increased appetite, increased body mass.
- Abnormal behaviour, aggression.
- Increased sensitivity of the skin to the sun and to UV light.
- Lack of energy.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

**Reporting of side effects**

If you get side effects, talk to doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety App (Medsafety X SAHPRA) and eReporting platform (who-umc-org) found on SAHPRA's website. By reporting side effects, you can help provide more information on the safety of NEOLORIDIN.

## 5. How to store NEOLORIDIN

- Store at or below 25 °C.
- Protect from light.
- Keep blister strips in the outer carton until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use the tablets after the expiry date printed on the blisters and containers. Decomposed products may be toxic.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

## 6. Contents of the pack and other information

**What NEOLORIDIN contains**

Each NEOLORIDIN 2,5 tablet contains 2,5 mg desloratadine.

The other inactive ingredients are aspartame, colloidal anhydrous silica, croscarmellose sodium, Indion 204 (containing methacrylic acid polymer with divinyl benzene and acrylic acid), mannitol, sodium stearyl fumarate and Trusil Mango Special powder (flavourant).

Each NEOLORIDIN 5 tablet contains 5 mg desloratadine.

The other inactive ingredients are aspartame, colloidal silicon dioxide, croscarmellose sodium, Indion 204 (containing methacrylic acid polymer with divinyl benzene and acrylic acid), mannitol, sodium stearyl fumarate, Sunset Yellow Lake I.H. (CI 15985) (colourant) and Trusil Mango Special powder (flavourant).

**What NEOLORIDIN looks like and contents of the pack**

NEOLORIDIN 2,5 tablets are white to light pink coloured, mottled, round, flat, uncoated with a break line on one side and plain on the other side. The tablets should be free of all physical defects.

NEOLORIDIN 5 tablets are orange coloured, round, flat, uncoated with a break line on one side and plain on the other side. The tablets should be free of all physical defects.

NEOLORIDIN tablets are packed in an aluminium/aluminium foil blister strip containing ten tablets. One or three blister strips are packed in an outer carton.

Pack sizes: 10 and 30.

**Holder of Certificate of Registration**

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**Dates of registration**

NEOLORIDIN 2,5: 10 December 2024

NEOLORIDIN 5: 05 October 2007

**This leaflet was last revised in**

Not revised yet.

**Registration numbers**

NEOLORIDIN 2,5: 55/5.7.1/0305

NEOLORIDIN 5: 41/5.7.1/0214