

## Package leaflet: Information for the user

### Nolpaza 20 mg gastro-resistant tablets Pantoprazole

**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.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse after 14 days.

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

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

#### **1. What Nolpaza is and what it is used for**

Nolpaza is a selective “proton pump inhibitor”, a medicine which reduces the amount of acid produced in your stomach. It is used for treating acid-related diseases of the stomach and intestine.

Nolpaza is used for short-term treatment of reflux disease (heartburn and gastric acid reflux symptoms) in adults.

Reflux means the acid returns from the stomach to the esophagus, which can therefore become inflamed and painful. It can cause symptoms such as painful burning sensation in the chest that may rise up to the throat (heartburn) or sour taste in the mouth (acid regurgitation).

The symptoms of acid reflux and heartburn usually begin to get worse one day after treatment with Nolpaza. This medicine has no immediate effect. Sometimes you may need to take the tablets 2 to 3 days before the symptoms get relieved.

You must talk to a doctor if you do not feel better or if you feel worse after 14 days.

#### **2. What you need to know before you take Nolpaza**

##### **Do not take Nolpaza:**

- If you are allergic to pantoprazole or any of the other ingredients of this medicine (listed in section 6).
- If you are using HIV protease inhibitors such as atazanavir, nelfinavir (medicines for HIV infection), see section "Other medicines and Nolpaza".

##### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Nolpaza:

- If you have had to continuously use any indigestion or heartburn medication for 4 or more weeks to treat the symptoms of a reflux;
- If you are over 55 years of age and use any indigestion medication daily;
- If you are over 55 years of age and you have a new symptom of reflux or the nature of the existing symptoms has recently changed;
- If you have had a stomach ulcer or some gastrointestinal surgery in the past;

- If you have liver problems or jaundice (yellowing of the skin or eyes);
- If you are under constant medical supervision due to serious illness or complaints;
- If you are planning an endoscopic examination or an exhaled air urea test in the near future;
- If you have ever had skin reactions after treatment with a Nolpaza-like medicine that reduces gastric acidity;
- If you are planning a specific blood test (chromogranin A);
- If you are taking pantoprazole at the same time as HIV protease inhibitors such as atazanavir, nelfinavir (for the treatment of HIV infection), ask your doctor for advice.

Do not use this medication without consulting your doctor for more than 4 weeks. If your symptoms of reflux disease (heartburn or gastric acid reflux) persist for more than 2 weeks, talk to your doctor who will decide on the long-term use of this medicine.

If you use Nolpaza for an extended period of time, it can lead to additional risks, for example;

- Decrease of vitamin B12 absorption and vitamin B12 deficiency if you already have lack of vitamin B12 in your body;
- Fracture of the femur, wrist or spine, especially if you already have osteoporosis or if you are using corticosteroids (which may increase the risk of osteoporosis);
- Decreased blood magnesium levels (potential symptoms: tiredness, involuntary muscle twitching, disorientation, seizures, dizziness, increased heart rate). Low levels of magnesium can also lead to a decrease in blood potassium or calcium. If you have been taking this medicine for more than 4 weeks, consult your doctor. Your doctor may decide to give you regular blood tests to monitor the level of magnesium.

**Tell your doctor immediately** (both before and after taking this medicine) if you notice any of the following symptoms that may indicate another serious illness:

- an unintentional loss of weight (weight loss that is not related to diet or exercise);
- vomiting, particularly if repeated; repeated vomiting
- vomiting blood (this may appear as dark coffee grounds in your vomit);
- blood in your stools (which may be black or tarry in appearance);
- difficulty in swallowing or pain when swallowing;
- you look pale and feel weak (anaemia);
- chest pain;
- stomach pain;
- severe and/or persistent diarrhoea, as Nolpaza has been associated with a small increase in infectious diarrhoea;
- if you get a skin rash, especially in areas that are exposed to sunlight, tell your doctor as soon as possible, as it may happen that you must stop treatment with Nolpaza. Be sure to also mention any other side effects, such as joint pain

In these cases, your doctor may decide that some tests need to be performed on you.

If you need to give a blood sample, tell your doctor that you are taking Nolpaza.

The symptoms of acid reflux and heartburn usually begin to get relief one day after the start of the treatment with Nolpaza. This medicine has no immediate effect.

Nolpaza should not be taken as a prophylactic medicine .

If you have had heartburn or symptoms of indigestion repeatedly for a long time, you should visit your doctor regularly.

### **Children and adolescents**

Nolpaza should not be used in children and adolescents under the age of 18 because there is not enough safety information for this age group.

### **Other medicines and Nolpaza**

Tell your doctor or pharmacist if you are taking or have recently taken or planned to take any other medicines, including medicines obtained without a prescription, herbal or homeopathic products. Nolpaza may influence the effectiveness of other medicines. Tell your doctor or pharmacist if you are taking any of the medicines containing the active substance listed below:

- HIV protease inhibitors such as atazanavir, nelfinavir (used to treat HIV infection). Do not take Nolpaza if you are using HIV protease inhibitors. See section "Do not take Nolpaza";
- ketoconazole, itraconazole and posaconazole (used to treat fungal infections) or erlotinib (used to treat certain cancers), as Nolpaza may prevent them and other medicines from acting;
- warfarin and phenprocoumon, which affect the thickening, or thinning of the blood. You may need further checks;
- methotrexate (used to treat rheumatoid arthritis, psoriasis, and cancer) – if you are taking methotrexate your doctor may temporarily stop your Nolpaza treatment because pantoprazole can increase levels of methotrexate in the blood.(a chemotherapy medicine used in high doses to treat cancer).

Do not take Nolpaza with other medicines that reduce the amount of acid produced in the stomach, such as other proton pump inhibitors (omeprazole, esomeprazole, lansoprazole or rabeprazole) or H<sub>2</sub> receptor antagonists (such as ranitidine and famotidine).

However, you can take Nolpaza, if necessary, with antacids (e.g., hydrotalcite, magaldrate, alginic acid, sodium carbonate, aluminum hydroxide, magnesium carbonate, or combinations thereof).

### **Nolpaza with food and drink**

Take the tablets 1 hour before a meal without chewing or breaking them and swallow them whole with some water.

### **Pregnancy and breast-feeding**

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.

Do not take Nolpaza if you are pregnant, breast-feeding or if you think you are pregnant or if you are planning to become pregnant.

### **Driving and using machines**

If you experience side effects like dizziness or disturbed vision, you should not drive or operate machines.

### **Nolpaza contains sorbitol and sodium**

This medicine contains 18 mg sorbitol in each tablet.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

## **3. How to take Nolpaza**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Take one tablet a day. Do not exceed the recommended dose of 20 mg pantoprazole daily.

The tablets should be taken for at least 2 to 3 consecutive days. Stop taking Nolpaza if your symptoms have completely disappeared. Symptoms of reflux and heartburn may also disappear after one-day treatment with Nolpaza, but this medicine is not intended to relieve symptoms immediately.

Consult your doctor if the symptoms persist after 2 weeks of continuous treatment.

Do not take Nolpaza tablets for more than 4 weeks without first consulting your doctor.

Take the tablet before a meal, at the same time each day. The tablet should be swallowed whole with

water.

The tablet should not be chewed or crushed.

### **Use in children and adolescents**

Children and adolescents under 18 years of age should not take Nolpaza tablets.

### **If you take more Nolpaza than you should**

You should tell your doctor or pharmacist right away. If possible, take the medicine and this leaflet with you. There are no known symptoms of overdose.

### **If you forget to take Nolpaza**

Do not take a double dose to make up for a forgotten dose. Take your next normal dose at the usual time.

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.

If you get any of the following **serious side effects, tell your doctor straight away** or contact the nearest hospital emergency department. Stop taking Nolpaza and take this leaflet and / or tablets with you:

### **Serious allergic reactions (frequency rare (may affect up to 1 in 1,000 people)):**

Hypersensitivity reactions, or so-called anaphylactoid reactions, anaphylactic shock and angioedema. Typical symptoms are:

- swelling of the face, lips, mouth, tongue and/or throat, which may result in difficulty in swallowing or breathing,
- hives (nettle rash),
- severe dizziness with very fast heartbeat and heavy sweating.

### **Serious skin conditions (frequency not known (frequency cannot be estimated from the available data)):**

- rash with swelling,
- blister rash or erosion of the top layer of the skin,
- erosion (including slight bleeding) of eyes, nose, mouth/lips or genitals and rapid deterioration of your general condition,
- a rash that occurs when exposed to sunlight.

### **Other serious conditions (frequency not known (frequency cannot be estimated from the available data)):**

- yellowing of the skin and whites of the eyes (due to severe damage to the liver),
- kidney problems such as painful urination with lower back pain and fever (serious inflammation of the kidneys, possibly progressing to kidney failure).

### **Frequency Rare (may affect up to 1 in 1,000 people)**

Severe reduction in number of white blood cells which makes infections more likely. Report any signs of sudden fever, sore throat extreme tiredness, which may be signs of infection.

### **Very rare (may affect up to 1 in 10,000 people)**

- A reduction in the number of blood platelets, which may cause you to bleed or bruise more than normal. Please report any unexplained bruising or bleeding to your doctor.

Other side effects are:

**Common** (may affect up to 1 in 10 people)

- Benign polyps in the stomach.

**Uncommon** (may affect up to 1 in 100 people)

- headache;
- dizziness;
- diarrhoea;
- feeling sick, vomiting;
- bloating and flatulence (wind);
- constipation;
- dry mouth;
- abdominal pain and discomfort;
- skin rash, exanthema, eruption;
- itching;
- feeling weak;
- feeling exhausted or generally unwell
- fracture of the hip, wrist or spine;
- sleep disorders;
- increase in hepatic enzyme activity in the blood test;
- hip, wrist and spine fracture.

**Rare** (may affect up to 1 in 1,000 people)

- disturbances in vision such as blurred vision;
- pain in the joints;
- muscle pains;
- weight changes;
- raised body temperature;
- swelling of the extremities;
- allergic reactions;
- depression;
- increase in blood bilirubin and lipids (seen in blood tests)
- breast enlargement in males;
- taste disorders.

**Very rare** (may affect up to 1 in 10,000 people)

- disorientation,
- a decrease in the number of white blood cells that can lead to an increase in infections,
- a decrease in the number of platelets that may cause weakness or bruising and increase the likelihood of infection

**Not known** (frequency cannot be estimated from the available data)

- hallucination, confusion (especially in patients with a history of these symptoms);
- decreased sodium level in blood;
- decreased magnesium level in blood,
- decreased calcium level in blood;
- decreased potassium level in blood;
- feeling of tingling, prickling, pins and needles, burning sensation or numbness;
- inflammation in the large bowel, that causes persistent watery diarrhoea;
- muscle spasm;
- rash, possibly with pain in the joints.

**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 [www.ravimiamet.ee](http://www.ravimiamet.ee). By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Nolpaza

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

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

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

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 Nolpaza contains

- The active substance is pantoprazole. Each gastro-resistant tablet contains 20 mg pantoprazole (as pantoprazole sodium sesquihydrate).
- The other ingredients are mannitol, crospovidone (type A, type B), sodium carbonate, sorbitol (E420), calcium stearate in the tablet core and hypromellose, povidone (K25), titanium dioxide (E171), yellow iron oxide (E172), propylene glycol, methacrylic acid - ethyl acrylate copolymer, sodium laurilsulfate, polysorbate 80, macrogol 6000 and talc in the film-coating. See section 2 "Nolpaza contains sorbitol and sodium".

### What Nolpaza looks like and contents of the pack

The 20 mg gastro-resistant tablets are light brownish yellow, oval, slightly biconvex tablets.

Nolpaza is available in blister packs packed in cartons.  
Pack of 7 tablets.

### Marketing Authorisation Holder and Manufacturer

#### Marketing Authorisation Holder

KRKA, d.d., Novo mesto  
Šmarješka cesta 6  
8501 Novo mesto  
Slovenia

#### Manufacturers

KRKA, d.d., Novo mesto  
Šmarješka cesta 6  
8501 Novo mesto  
Slovenia

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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder  
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The following lifestyle and diet changes can help relieve heartburn or other symptoms caused by acid reflux:

- Do not eat too much at once.
- Eat slowly.
- Stop smoking.
- Reduce alcohol and caffeine intake.
- Reduce your weight (if you are overweight).
- Do not wear narrow clothing or pinch straps or belts.
- Try not to eat for three hours before bedtime.
- Raise your head (if you have nightly symptoms).
- Reduce your intake of heartburn foods. Such foods include, for example, chocolate, peppermint, greasy and fried food, sour food, spicy food, citrus fruits and fruit juices, tomatoes.