

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

### **Nolpacid 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.**

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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 2 weeks.

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

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

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

Nolpacid contains the active substance pantoprazole, which blocks the ‘pump’ that produces stomach acid. Hence it reduces the amount of acid in your stomach.

Nolpacid is used for the short-term treatment of reflux symptoms (for example heartburn, acid regurgitation) in adults.

Reflux is the backflow of acid from the stomach into the gullet (“foodpipe”), which may become inflamed and painful. This may cause you symptoms such as a painful burning sensation in the chest rising up to the throat (heartburn) and a sour taste in the mouth (acid regurgitation).

You may experience relief from your acid reflux and heartburn symptoms after just one day of treatment with Nolpacid, but this medicine is not meant to bring immediate relief. It may be necessary to take the tablets for 2–3 consecutive days to relieve the symptoms.

You must talk to a doctor if you do not feel better or if you feel worse after 2 weeks.

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

##### **Do not take Nolpacid:**

- if you are allergic to pantoprazole or any of the other ingredients of this medicine (listed in section 6),
- if you are taking HIV protease inhibitors such as atazanavir; nelfinavir (for the treatment of HIV-infection) See ‘Other medicines and Nolpacid’.

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

Talk to your doctor or pharmacist before taking Nolpacid.

Talk to your doctor first if:

- you have been treated for heartburn or indigestion continuously for 4 or more weeks
- you are over 55 years old and taking non-prescription indigestion treatment on a daily basis

- you are over 55 years old with any new or recently changed reflux symptoms
- you have previously had a gastric ulcer or stomach surgery
- you have liver problems or jaundice (yellowing of skin or eyes)
- you regularly see your doctor for serious complaints or conditions
- you are due to have an endoscopy or a breath test called a C-urea test
- you have ever had a skin reaction after treatment with a medicine similar to Nolpacid that reduces stomach acid.
- you are due to have a specific blood test (Chromogranin A).
- you are taking HIV protease inhibitors such as atazanavir; nelfinavir (for the treatment of HIV-infection) at the same time as pantoprazole, ask your doctor for specific advice.

Do not take this product for longer than 4 weeks without consulting your doctor. If your reflux symptoms (heartburn or acid regurgitation) persist for longer than 2 weeks, consult your doctor who will decide about the need for long-term intake of this medicinal product.

If you take Nolpacid for longer periods, this may cause additional risks, such as:

- reduced absorption of Vitamin B12, and Vitamin B12 deficiency if you already have low body stores of Vitamin B12. Please contact your doctor if you notice any of the following symptoms, which could indicate low levels of vitamin B12:
  - Extreme tiredness or lack of energy
  - Pins and needles
  - Sore or red tongue, mouth ulcers
  - Muscle weakness
  - Disturbed vision
  - Problems with memory, confusion, depression
- fracture of your hip, wrist or spine, especially if you already suffer from osteoporosis (reduced bone density) or if your doctor has told you that you are at risk of getting osteoporosis (for example, if you are taking steroids).
- falling magnesium levels in your blood (potential symptoms: fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness, increased heart rate). Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood. You should talk to your doctor if you have been using this product for more than 4 weeks. Your doctor may decide to perform regular blood tests to monitor your levels of magnesium.

**Tell your doctor immediately**, before or after taking this medicine, if you notice any of the following symptoms, which could be a sign of another, more serious, disease:

- an unintentional loss of weight (not related to a diet or an exercise programme)
- vomiting, particularly if repeated
- vomiting blood; this may appear as dark coffee grounds in your vomit
- you notice 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, because this medicine has been associated with a small increase in infectious diarrhoea.
- if you get a rash on your skin, especially in areas exposed to the sun tell your doctor as soon as you can, as you may need to stop your treatment with Nolpacid. Remember to also mention any other ill-effects like pain in your joints.
- serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS) and erythema multiforme have been reported in association with pantoprazole treatment. Stop using pantoprazole and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Your doctor may decide that you need some tests.

If you are due to have a blood test, tell your doctor that you are taking this medicine.

You may experience relief from your acid reflux and heartburn symptoms after just one day of treatment with Nolpacid, but this medicine is not meant to bring immediate relief. You should not take it as a preventive measure.

If you have been suffering from repetitive heartburn or indigestion symptoms for some time, remember to see your doctor regularly.

### **Children and adolescents**

Nolpacid should not be used by children and adolescents under 18 years of age due to a lack of safety information in this younger age group.

### **Other medicines and Nolpacid**

Tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use any other medicines including medicines obtained without a prescription. This also includes herbal or homeopathic remedies.

Nolpacid may stop certain other medicines from working properly. Tell your doctor or pharmacist if you are using any medicines containing one of the following active substances:

- HIV protease inhibitors such as atazanavir, nelfinavir (for the treatment of HIV-infection). You must not use Nolpacid if you are taking HIV protease inhibitors. See 'Do not take Nolpacid'.
- ketoconazole (used for fungal infections).
- warfarin and phenprocoumon (used to thin blood and prevent clots). You may need further blood tests.
- methotrexate (used to treat rheumatoid arthritis, psoriasis, and cancer) – if you are taking methotrexate your doctor may temporarily stop your Nolpacid treatment because pantoprazole can increase levels of methotrexate in the blood.

Do not take Nolpacid with other medicines which limit the amount of acid produced in your stomach, such as another proton pump inhibitor (omeprazole, lansoprazole or rabeprazole) or an H<sub>2</sub> antagonist (e.g. ranitidine, famotidine).

However, you may take Nolpacid with antacids (e.g. magaldrate, alginic acid, sodium bicarbonate, aluminium hydroxide, magnesium carbonate, or combinations thereof), if needed.

Talk to your doctor before taking Nolpacid if you are due to have a specific urine test (for THC; Tetrahydrocannabinol).

### **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.

You should not take this medicine if you are pregnant or while-breastfeeding.

### **Driving and using machines**

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

### **Nolpacid contains sorbitol (E420) 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 Nolpacid**

Always take this medicine exactly as described in this leaflet or 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 this recommended dose of 20 mg pantoprazole daily.

You should take this medicine for at least 2–3 consecutive days. Stop taking Nolpacid when you are completely symptom-free. You may experience relief from your acid reflux and heartburn symptoms after just one day of treatment with Nolpacid, but this medicine is not meant to bring immediate relief.

If you have no symptom-relief after taking this medicine for 2 weeks continuously, consult your doctor.

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

Take the tablet before a meal, at the same time every day. You should swallow the tablet whole with some water. Do not chew or break the tablet.

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

Tell your doctor or pharmacist straight away, if you have taken more than the recommended dose. If possible, take your medicine and this leaflet with you.

#### **If you forget to take Nolpacid**

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

**Tell your doctor immediately** or contact the casualty department at your nearest hospital, if you get any of the following **serious side effects**. Stop taking this medicine straight away, but take this leaflet and/or the tablets with you.

- **Serious allergic reactions (rare:** may affect up to 1 in 1,000 people): Hypersensitivity reactions, so-called anaphylactic reactions, anaphylactic shock and angioedema. Typical symptoms are: swelling of the face, lips, mouth, tongue and/or throat, which may cause difficulty in swallowing or breathing, hives (nettle rash), severe dizziness with very fast heartbeat and heavy sweating.
- **Serious skin reactions (frequency not known:** frequency cannot be estimated from the available data): you may notice one or more of the following - rash with swelling, blistering or peeling of the skin, losing skin and bleeding around eyes, nose, mouth or genitals and rapid deterioration of your general health, or rash when exposed to the sun. You may also have joint pain or flu-like symptoms, a fever, swollen glands (e.g. in the armpit) and blood tests may show changes in certain white blood cells or liver enzymes.
  - reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome, toxic epidermal necrolysis).
  - widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).
- **Other serious reactions (frequency not known):** yellowing of the skin and eyes (due to severe liver damage), or fever, rash, and enlarged kidneys sometimes with painful urination, and lower back pain (serious inflammation of the kidneys), possibly leading to kidney failure.

Other side effects include:

- **Common side effects** (may affect up to 1 in 10 people): benign polyps in the stomach.
- **Uncommon side effects** (may affect up to 1 in 100 people): headache; dizziness; diarrhoea; feeling sick, vomiting; bloating and flatulence (wind); constipation; dry mouth; bellyache and discomfort; skin rash or hives; itching; feeling weak,

- exhausted or generally unwell; sleep disorders; increase in liver enzymes in a blood test; fracture of wrist, hip and spine.
- **Rare side effects** (may affect up to 1 in 1,000 people):  
distortion or complete lack of the sense of taste; disturbances in vision such as blurred vision; pain in the joints; muscle pains; weight changes; raised body temperature; swelling of the extremities; depression; increased bilirubin and fat levels in blood (seen in blood tests); breast enlargement in males; high fever and a sharp drop in circulating granular white blood cells (seen in blood tests).
- **Very rare side effects** (may affect up to 1 in 10,000 people):  
disorientation; reduction in the number of blood platelets, which may cause you to bleed or bruise more than normal; reduction in the number of white blood cells, which may lead to more frequent infections; coexisting abnormal reduction in the number of red and white blood cells, as well as platelets (seen in blood tests).
- **Frequency not known:**  
hallucination, confusion (especially in patients with a history of these symptoms); decreased level of sodium, magnesium, calcium or potassium in blood (see section 2); rash, possibly with pain in the joints; feeling of tingling, prickling, pins and needles, burning sensation or numbness; inflammation in the large bowel, that causes persistent watery diarrhoea.

### Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: [www.hpra.ie](http://www.hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Nolpacid

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

Store in the original package in order to protect from moisture.

This medicinal product does not require any special temperature storage conditions.

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 Nolpacid 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 B), sodium carbonate, sorbitol (E420) and calcium stearate in the tablet core, and hypromellose, povidone, titanium dioxide (E171), yellow iron oxide (E172), propylene glycol, methacrylic acid - ethyl acrylate copolymer (1:1) dispersion 30 per cent, sodium laurilsulfate, polysorbate 80, macrogol 6000 and talc in the film-coating.

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

The 20 mg gastro-resistant tablets are light yellowish brown, oval (3 mm x 9 mm), slightly biconvex film-coated tablets.

Nolpacid is available in boxes of 7 and 14 gastro-resistant tablets in blister packs of 7 or 14 tablets.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

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

**This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:**

United Kingdom (Northern Ireland)	Pantoprazole Krka
Ireland	Nolpacid
Latvia	Nolpaza Control
Bulgaria, Austria	Nolpaza control
Italy	Sedipanto

**This leaflet was last revised in**

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The following recommendations for lifestyle and dietary changes may also help to relieve heartburn or acid related symptoms.

- Avoid large meals
- Eat slowly
- Stop smoking
- Reduce alcohol and caffeine consumption
- Reduce weight (if overweight)
- Avoid tight-fitting clothing or belts
- Avoid eating less than three hours before bedtime
- Elevate bedhead (if you suffer from nocturnal symptoms)
- Reduce intake of food that can cause heartburn. These might include: Chocolate, peppermint, spearmint, fatty and fried food, acidic food, spicy food, citrus fruits and fruit juices, tomatoes.