smer branja kode

70 mm ± 0,5 mm

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.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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:

Adults and adolescents 12 years of age and above:
- Treating symptoms (e.g. heartburn, acid regurgitation, pain on swallowing) associated to gastro-oesophageal reflux disease caused by reflux of acid from the stomach.
- Long-term management of reflux oesophagitis (inflammation of the oesophagus accompanied by the regurgitation of stomach acid) and preventing its return.

Adults:
- Preventing duodenal and stomach ulcers caused by non-steroidal anti-inflammatory drugs (NSAIDs, for example, ibuprofen) in patients at risk who need to take NSAIDs continuously.

2. What you need to know before you take Nolpaza

Do not take Nolpaza
- if you are allergic to pantoprazole, sorbitol or any of the other ingredients of this medicine (listed in section 6);
- if you are allergic to medicines containing other proton pump inhibitors.

Warnings and precautions

Talk to your doctor or pharmacist before taking Nolpaza.
- If you have severe liver problems. Please tell your doctor if you have ever had problems with your liver. He will check your liver enzymes more frequently, especially when you are taking Nolpaza as a long-term treatment. In the case of a rise of liver enzymes the treatment should be stopped.
- If you need to take medicines called NSAIDs continuously and receive Nolpaza because you have an increased risk of developing stomach and intestinal complications. Any increased risk will be assessed according to your own personal risk factors such as your age (65 years old or more), a history of stomach or duodenal ulcers or of stomach or intestinal bleeding.
- If you have reduced body stores or risk factors for reduced vitamin B12 and receive pantoprazole long-term treatment. As with all acid reducing agents, pantoprazole may lead to a reduced absorption of vitamin B12.
- If you are taking HIV protease inhibitors such as atazanavir (for the treatment of HIV-infection) at the same time as pantoprazole, ask your doctor for specific advice.
- Taking a proton pump inhibitor like pantoprazole, especially over a period of more than one year, may slightly increase your risk of fracture in the hip, wrist or spine.
- Tell your doctor if you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis).
- If you are on Nolpaza for more than three months it is possible that the levels of magnesium in your blood may fall. Low levels of magnesium can be seen as fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness or increased heart rate. If you get any of these symptoms, please tell your doctor promptly. Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood. Your doctor may decide to perform regular blood tests to monitor your levels of magnesium.
- If you have ever had a skin reaction after treatment with a medicine similar to Nolpaza that reduces stomach acid.
- 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 Nolpaza. Remember to also mention any other ill-effects like pain in your joints.
- If you are due to have a specific blood test (Chromogranin A)

Tell your doctor immediately if you notice any of the following symptoms:
- an unintentional loss of weight
- 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, as Nolpaza has been associated with a small increase in infectious diarrhoea.

Your doctor may decide that you need some tests to rule out malignant disease because pantoprazole also alleviates the symptoms of cancer and could cause delay in diagnosing it. If your symptoms continue in spite of your treatment, further investigations will be considered.

If you take Nolpaza on a long-term basis (longer than 1 year) your doctor will probably keep you under regular surveillance. You should report any new and exceptional symptoms and circumstances whenever you see your doctor.

Children and adolescents

These tablets are not recommended for use in children below 12 years.

Other medicines and Nolpaza

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

Nolpaza may influence the effectiveness of other medicines, so tell your doctor if you are taking
- Medicines such as ketoconazole, itraconazole and posaconazole (used to treat fungal infections) or erlotinib (used for certain types of cancer) because Nolpaza may stop these and other medicines from working properly.
- Warfarin and phenprocoumon, which affect the thickening, or thinning of the blood. You may need further checks.
- Medicines used to treat HIV-infection, such as atazanavir.
- 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.
- Fluvoxamine (used to treat depression and other psychiatric diseases) – if you are taking fluvoxamine your doctor may reduce the dose.
- Rifampicin (used to treat infections).
- St John's wort (Hypericum perforatum) (used to treat mild depression).

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.

There are no adequate data from the use of pantoprazole in pregnant women. Excretion into human milk has been reported. You should use this medicine only if your doctor considers the benefit for you greater than the potential risk for your unborn child or baby.

Driving and using machines

Nolpaza has no or negligible influence on the ability to drive and use 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.

When and how should you take Nolpaza?

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

Unless told otherwise by your doctor, the recommended dose is:

Adults and adolescents 12 years of age and above:

To treat symptoms (e.g. heartburn, acid regurgitation, pain on swallowing) associated to gastro-oesophageal reflux disease

The recommended dose is one tablet a day. This dose usually brings relief within 2 - 4 weeks – at most after another 4 weeks. Your doctor will tell you how long to continue taking the medicine. After this any recurring symptoms can be controlled by **taking one tablet daily**, when required.

For long-term management and for preventing the return of reflux oesophagitis

The recommended dose is one tablet a day. If the illness returns, your doctor can double the dose, in which case you can use Nolpaza 40 mg tablets instead, one a day. After healing, you can reduce the dose back again to one tablet 20 mg a day.

Adults:

To prevent duodenal and stomach ulcers in patients who need to take NSAIDs continuously

The recommended dose is one tablet a day.

Special patient groups:

If you suffer from severe liver problems, you should not take more than one 20 mg tablet a day.

Use in children and adolescents

Children below 12 years.
These tablets are not recommended for use in children below 12 years.

Navodila prepognjena na sredini z vidno prvo stranjo (naslovom); pharma kodi, ki izhajata iz sredine navodila, morata biti vidni!

- *PMS-433U-KRKA*

KRKA
Article name.: PL.NOLPAZA 20MG IE
Prepared by: A. Mohorič
Date: 04.09.2019

smer vlaken

70 mm ± 0,5 mm

smer branja kode

DPMockUp088437_1

smer branja kode

130 mm ± 0,5 mm

If you take more Nolpaza than you should
Tell your doctor or pharmacist. 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 stop taking Nolpaza
Do not stop taking these tablets without first talking to your doctor or pharmacist.

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 side effects, stop taking these tablets and tell your doctor immediately, or contact the casualty department at your nearest hospital:

- **Serious allergic reactions (frequency rare:** may affect up to 1 in 1,000 people**):** swelling of the tongue and/or throat, difficulty in swallowing, hives (nettle rash), difficulties in breathing, allergic facial swelling (Quincke's oedema / angioedema), severe dizziness with very fast heartbeat and heavy sweating.
- **Serious skin conditions (frequency not known:** frequency cannot be estimated from the available data**):** blistering of the skin and rapid deterioration of your general condition, erosion (including slight bleeding) of eyes, nose, mouth/lips or genitals (Stevens-Johnson-Syndrome, Lyell-Syndrome, Erythema multiforme) and sensitivity to light.
- **Other serious conditions (frequency not known:** frequency cannot be estimated from the available data**):** yellowing of the skin or whites of the eyes (severe damage to liver cells, jaundice) or fever, rash, and enlarged kidneys sometimes with painful urination and lower back pain (serious inflammation of the kidneys), possibly leading to kidney failure.
If you are on pantoprazole for more than three months it is possible that the levels of magnesium in your blood may fall. Low levels of magnesium can be seen as fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness, increased heart rate. If you get any of these symptoms, please tell your doctor promptly. Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood. Your doctor may decide to perform regular blood tests to monitor your levels of magnesium.

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; fracture of the hip, wrist or spine; feeling weak, exhausted or generally unwell; sleep disorders.
- **Rare** (may affect up to 1 in 1,000 people)
Disturbances in vision such as blurred vision; hives; pain in the joints; muscle pains; weight changes; raised body temperature; swelling of the extremities (peripheral oedema); allergic reactions; depression; breast enlargement in males; taste disorders.
- **Very Rare** (may affect up to 1 in 10,000 people)
Disorientation.
- **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 calcium level in blood; decreased potassium level in blood; tingling or numbness in the hands or feet; inflammation in the large bowel, that causes persistent watery diarrhoea; muscle spasm; rash, possibly with pain in the joints.

Side effects identified through blood tests:
- **Uncommon** (may affect up to 1 in 100 people)
An increase in liver enzymes.
- **Rare** (may affect up to 1 in 1,000 people)
An increase in bilirubin; increased fats in the blood; severe reduction in number of white blood cells which makes infections more likely.
- **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; a reduction in the number of white blood cells, which may lead to more frequent infections; severe reduction in blood cells which can cause weakness, bruising or make infections more likely.

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

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.

Blister pack: Store in the original package in order to protect from moisture.

Container: Keep the container tightly closed in order to protect from moisture.
After first opening of the container, the product should be used within 3 months.

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
- Each gastro-resistant tablet contains 20 mg pantoprazole (as pantoprazole sodium sesquihydrate).
- The other ingredients are mannitol, crospovidone (type A, type B), anhydrous 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.

What Nolpaza looks like and contents of the pack
The 20 mg gastro-resistant tablets are light brownish yellow, oval, slightly biconvex tablets.

Pack sizes:
Boxes of 7, 14, 15, 28, 30, 56, 60, 84, 100, 100 x 1, 112 and 140 gastro-resistant tablets in blister packs.
A plastic container of 250 gastro-resistant tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
KRKA, d.d., Novo mesto, Šmarješka cesta 6,
8501 Novo mesto, Slovenia

Manufacturer
KRKA, d.d., Novo mesto, Šmarješka cesta 6,
8501 Novo mesto, Slovenia
TAD Pharma GmbH, Heinz-Lohmann-Str. 5,
D-27472 Cuxhaven, Germany

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

Name of the Member State	Name of the medicinal product
United Kingdom	Pantoprazole
Italy	Nolpaza
Ireland	Nolpaza
Spain	Nolpaza
Bulgaria	Nolpaza
Slovak Republic	Pantoprazol Krka
Poland	Pantoprazol Krka
Czech Republic	Pantoprazol Krka
Hungary	Pantoprazol Krka
Slovenia	Pantoprazol Krka
Portugal	Nolpaza
Latvia	Nolpantol
Romania	Nolpaza

This leaflet was last revised in

KRKA

xxxxxx

smer vlaken

130 mm ± 0,5 mm

smer branja kode