

## PACKAGE LEAFLET: INFORMATION FOR THE USER

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### NOPLAZA CONTROL

20 mg gastro-resistant tablets

PANTOPRAZOLE

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*• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.*

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*• 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 •*

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#### What is in this leaflet?

1. What NOPLAZA CONTROL is and what it is used for
2. Before you take NOPLAZA CONTROL
3. How to take NOPLAZA CONTROL
4. Possible side effects
5. How to store NOPLAZA CONTROL

#### 1. WHAT NOPLAZA CONTROL IS AND WHAT IS IT USED FOR

Nolpaza Control contains the active substance pantoprazole (as sodium sesquihydrate).

Pantoprazole 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.

Pantoprazole is used to treat adults and adolescents 12 years of age and above for:

- 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.

Pantoprazole is used to treat adults for:

- 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. BEFORE YOU TAKE NOPLAZA CONTROL

### ***Do not take Pantoprazole***

- If you are allergic (hypersensitive) to pantoprazole or to any of the other ingredients of Nolpaza Control.
- If you are allergic to medicines containing other proton pump inhibitors.

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

Talk to your doctor or pharmacist before taking Pantoprazole

- 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 Pantoprazole 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 Pantoprazole 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 long-term treatment with pantoprazole. As with all acid reducing agents, pantoprazole may lead to a reduced absorption of vitamin B12.
- If you are taking a medicine containing atazanavir (for the treatment of HIV-infection) at the same time as pantoprazole, ask your doctor for specific advice.
- People who take multiple daily doses of proton pump inhibitor medicines for a long period of time (a year or longer) may have an increased risk of fractures of the hip, wrist or spine. Talk to your doctor about your risk of bone fracture if you take Pantoprazole.
- If you have low magnesium levels in your body. This problem can be serious. Low magnesium can happen in some people who take a proton pump inhibitor medicine for at least 3 months. If low magnesium levels happen, it is usually after a year of treatment. You may or may not have symptoms of low 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
- difficulty in swallowing or pain when swallowing
- you look pale and feel weak (anaemia)
- you notice blood in your stools
- chest pain
- stomach pain
- severe and/or persistent diarrhoea, because this medicine 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 Pantoprazole 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**

Pantoprazole is not recommended for use in children as it has not been proven to work in children below 12 years of age.

### **Other medicines and Pantoprazole**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

- Medicines such as ketoconazole, itraconazole and posaconazole (used to treat fungal infections) or erlotinib (used for certain types of cancer) because Pantoprazole 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.
- Atazanavir (used to treat HIV-infection) and other medicines used to treat HIV.
- Methotrexate (used to treat rheumatoid arthritis, psoriasis, and cancer) – if you are taking methotrexate your doctor may temporarily stop your Pantoprazole treatment because pantoprazole can increase levels of methotrexate in the blood.

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

There are no adequate data from the use of pantoprazole in pregnant women. Excretion into human milk has been reported. 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 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**

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

## **3. HOW TO TAKE NOPLAZA CONTROL**

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

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 gastroesophageal reflux disease

The usual 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 usual dose is one tablet a day. If the illness returns, your doctor can double the dose, in which case you can use Pantoprazole 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 usual dose is one tablet a day.

#### **Patients with liver problems**

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

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

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

### **Method of administration**

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

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

Tell your doctor or pharmacist. There are no known symptoms of overdose.

### ***If you forget to take Pantoprazole***

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 Pantoprazole***

Do not stop taking these tablets without first talking to your doctor or pharmacist.

If you have any further questions about 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):** 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):** blistering of the skin and rapid deterioration of your general condition, erosion (including slight bleeding) of eyes, nose, mouth/lips or genitals (StevensJohnson-Syndrome, Lyell-Syndrome, Erythema multiforme) and sensitivity to light.
- **Other serious conditions (frequency not known):** 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).

### **Other side effects are:**

#### **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, exhausted or generally unwell; sleep disorders.

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).

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

Distortion or complete lack of the sense of taste; disturbances in vision such as blurred vision; hives; pain in the joints; muscle pains; weight changes; raised body temperature; high fever; swelling of the extremities (peripheral oedema); allergic reactions; depression; breast enlargement in males.

#### **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, feeling of tingling, prickling, pins and needles, burning sensation or numbness; low levels of potassium

which can cause muscle weakness, twitching or abnormal heart rhythm; muscle spasm or cramps; low levels of calcium..

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 (see section 2).

**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 fat levels in blood; sharp drop in circulating granular white blood cells, associated with high fever.

**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; coexisting abnormal reduction in the number of red and white blood cells, as well as platelets.

***Reporting of side effects***

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. By reporting side effects you can help provide more information on the safety of this medicine.

***5. HOW TO STORE NOPLAZA CONTROL***

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 carton and the container after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special 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 to protect the environment.