

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### Pantoprazole **Nycomed** 20 mg gastro-resistant tablets

Pantoprazole

#### **Read all of this leaflet carefully before you start taking this medicine.**

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

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### **1. WHAT PANTOPRAZOLE NYCOMED IS AND WHAT IT IS USED FOR**

Pantoprazole Nycomed 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 disease of the stomach and intestine.

#### **Pantoprazole Nycomed 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. BEFORE YOU TAKE PANTOPRAZOLE NYCOMED**

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

- If you are allergic (hypersensitive) to pantoprazole or to any of the other ingredients of Pantoprazole Nycomed (see section 6).
- If you are allergic to medicines containing other proton pump inhibitors.

#### **Take special care with Pantoprazole Nycomed**

- 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 Nycomed as a long-term treatment. In the case of rise of liver enzymes the treatment should be stopped.
- If you need to take medicines called NSAIDs continuously and receive Pantoprazole Nycomed 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 and 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.

**Tell your doctor immediately** if you notice any of the following symptoms:

- an unintentional loss of weight
- repeated vomiting
- difficulty in swallowing
- vomiting blood
- you look pale and feel weak (anaemia)
- you notice blood in your stools
- severe and/or persistent diarrhoea, as Pantoprazole Nycomed 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 Nycomed 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.

### **Taking other medicines**

Pantoprazole Nycomed 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 Pantoprazole Nycomed 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).

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

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

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

If you are pregnant, or think you may be pregnant, or if you are breast-feeding, 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.

Ask your doctor or pharmacist for advice before taking any medicine.

### **Driving and using machines**

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

### 3. HOW TO TAKE PANTOPRAZOLE NYCOMED

Always take Pantoprazole Nycomed exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

#### **When and how should you take Pantoprazole Nycomed?**

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 usual 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 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 Nycomed 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.

Special patient groups:

- If you suffer from severe liver problems, you should not take more than one 20 mg tablet a day.
- Children below 12 years. These tablets are not recommended for use in children below 12 years.

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

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

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

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

#### **If you stop taking Pantoprazole Nycomed**

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 product, ask your doctor or pharmacist.

### 4. POSSIBLE SIDE EFFECTS

Like all medicines, Pantoprazole Nycomed can cause side effects, although not everybody gets them.

The frequency of possible side effects listed below is defined using the following convention:

very common (affects more than 1 user in 10)

common (affects 1 to 10 users in 100)

uncommon (affects 1 to 10 users in 1,000)

rare (affects 1 to 10 users in 10, 000)

very rare (affects less than 1 user in 10, 000)

not known (frequency cannot be estimated from the available data)

**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 (Stevens-Johnson-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 known side effects are:**

- **Uncommon** (affects 1 to 10 users in 1,000)  
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** (affects 1 to 10 users in 10, 000)  
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** (affects less than 1 user in 10, 000)  
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.  
If you are on Pantoprazole Nycomed 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.

**Side effects identified through blood tests:**

- **Uncommon** (affects 1 to 10 users in 1,000)  
an increase in liver enzymes
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- **Rare** (affects 1 to 10 users in 10, 000)  
an increase in bilirubin; increased fat levels in blood; sharp drop in circulating granular white blood cells, associated with high fever.
- **Very Rare** (affects less than 1 user in 10,000)  
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.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

## **5. HOW TO STORE PANTOPRAZOLE NYCOMED**

Keep out of the reach and sight of children.

Do not use Pantoprazole Nycomed 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.

For HDPE bottles: do not use tablets beyond 2 months after first opening of the bottle.

This medicine does not require any special storage conditions.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## **6. FURTHER INFORMATION**

### **What Pantoprazole Nycomed contains**

- The active substance is pantoprazole. Each gastro-resistant tablet contains 20 mg of pantoprazole (as sodium sesquihydrate).
- The other ingredients are:
  - Core: sodium carbonate (anhydrous), mannitol, crospovidone, povidone K90, calcium stearate.
  - Coating: hypromellose, povidone K25, titanium dioxide (E171), yellow iron oxide (E172), propylene glycol, methacrylic acid-ethyl acrylate copolymer (1:1), polysorbate 80, sodium laurilsulfate, triethyl citrate
  - Printing ink: shellac, red, black and yellow iron oxide (E172) and ammonia solution, concentrated.

### **What Pantoprazole Nycomed looks like and contents of the pack**

Yellow, oval, biconvex film-coated tablet imprinted with "P 20" on one side.

Packs: bottles (high density polyethylene bottle with low density polyethylene screw cap closure) and blister, (ALU/ALU blister without cardboard reinforcement or , with cardboard reinforcement (blister wallet).

Pantoprazole Nycomed are available in the following pack sizes:

Packs with 7, 10, 14, 15, 24, 28, 30, 48, 56, 60, 84, 90, 98, 100, 112, 168 gastro-resistant tablets.

Hospital packs with 50, 56, 84, 90, 112, 140, 140 (10x14 or 5x28), 280 (20x14 or 10x28), 500, 700 (5x140) gastro-resistant tablets.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder**

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**This leaflet was last approved in 11/2012.**

Detailed information on this medicinal product is available on the website of the Heads of Medicines Agencies (HMA) <http://www.hma.eu>