Patient Information Leaflet

SCHEDULING STATUS: S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

PROPRIETARY NAME (AND DOSAGE FORM):

MYLAN PANTOPRAZOLE 20 mg Enteric-coated tablets

MYLAN PANTOPRAZOLE 40 mg Enteric-coated tablets

Pantoprazole sodium sesquihydrate

Read all of this leaflet carefully before you start taking MYLAN PANTOPRAZOLE.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **MYLAN PANTOPRAZOLE** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT MYLAN PANTOPRAZOLE CONTAINS:

• The active substance is pantoprazole.

MYLAN PANTOPRAZOLE 20 mg - Each tablet contains 22,550 mg pantoprazole sodium sesquihydrate equivalent to 20 mg pantoprazole.

Contains lactose monohydrate 19,06 mg

MYLAN PANTOPRAZOLE 40 mg - Each tablet contains 45,1 mg pantoprazole sodium sesquihydrate equivalent to 40 mg pantoprazole.
Contains lactose monohydrate 38,12 mg

The other ingredients in the tablets are: croscarmellose sodium, magnesium stearate, microcrystalline cellulose, purified water, silica colloidal anhydrous.

2. WHAT MYLAN PANTOPRAZOLE IS USED FOR:

Pantoprazole belongs to a group of medicines for treating acid-related diseases of the stomach and intestine. They are a “selective proton pump inhibitor”, something which reduces the amount of acid produced in your stomach.

MYLAN PANTOPRAZOLE 40 mg is used for the short-term treatment of duodenal ulcer, gastric ulcer and reflux oesophagitis (an inflammation of your oesophagus accompanied by the regurgitating of stomach acid).

MYLAN PANTOPRAZOLE 40 mg is used for the treatment of Zollinger-Ellison syndrome.

MYLAN PANTOPRAZOLE 20 mg is used for treating mild forms of oesophageal disease caused by reflux of acid from the stomach (with or without mild inflammation of the oesophagus) and associated systems (e.g. heartburn, acid regurgitation, pain on swallowing) and healing of mild gastro-oesophageal reflux disease (GERD).

MYLAN PANTOPRAZOLE 20 mg is used for long-term management of relapse in reflux oesophagitis (inflammation of the oesophagus accompanied by the regurgitation of

stomach acid) and preventing its return.

MYLAN PANTOPRAZOLE 20 mg is used for preventing duodenal and stomach ulcers caused by non-steroidal anti-inflammatory medicines (NSAIDs) in patients who need to take NSAIDs continuously.

3. BEFORE YOU TAKE MYLAN PANTOPRAZOLE:

Do not take MYLAN PANTOPRAZOLE:

- If you are hypersensitive (allergic) to pantoprazole or any of the other ingredients of **MYLAN PANTOPRAZOLE 20 mg** and **40 mg** tablets.
- If you have severe liver problems.
- Children: Safety and efficacy in children have not been established.
- If you take a medicine containing atazanavir (for the treatment of HIV-infection) at the same time.

Take special care with MYLAN PANTOPRAZOLE:

- If you have **severe** liver problems. Please tell your doctor if you have ever had problems with your liver. Your doctor may want to check your liver enzymes more frequently. The dose may be reduced or the treatment may be stopped.
- If you need to take medicines called NSAIDs continuously with **MYLAN PANTOPRAZOLE 20 mg** because you have an increased risk of developing stomach and intestinal complications.
- If you have reduced body stores or risk factors for reduced vitamin B12 as **MYLAN PANTOPRAZOLE** may lead to reduced absorption of vitamin B12.
- If you have kidney problems or if you experience symptoms such as blood in the urine, fever, increased or decreased urine output, drowsiness and confusion, nausea and vomiting, rash, swelling of any area of the body and weight gain from retaining fluid (interstitial

nephritis).

Taking MYLAN PANTOPRAZOLE with food and drink:

Swallow the **MYLAN PANTOPRAZOLE** tablets with a glass of water before or during breakfast.

Pregnancy and Breastfeeding:

MYLAN PANTOPRAZOLE should not be taken by pregnant or breastfeeding mothers.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **MYLAN PANTOPRAZOLE.**

Important information about some of the ingredients of MYLAN PANTOPRAZOLE:

MYLAN PANTOPRAZOLE contains lactose. Patients with the rare hereditary conditions of lactose/fructose or galactose intolerance should not take **MYLAN PANTOPRAZOLE.**

Taking other medicines with MYLAN PANTOPRAZOLE:

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

- Ketoconazole (antifungal medicine)
- Ampicillin esters and iron salts (antibiotic)
- Diazepam (tranquilliser)
- Theophylline (bronchial asthma)
- Digoxin (for treating certain heart conditions)
- Phenytoin (for treating certain heart conditions)
- Carbamazepine (epilepsy)
- Diclofenac (non-steroidal anti-inflammatory medicine)

• Nifedipine (for treating certain heart conditions)

• Piroxicam (non-steroidal anti-inflammatory medicine)

• Metoprolol (for treating certain heart conditions)

• Glibenclamide

• Ethanol (alcohol)

• Caffeine

• Warfarin (anticoagulant to thin the blood)

• Oral contraceptives (to prevent pregnancy)

4. HOW TO TAKE MYLAN PANTOPRAZOLE:

Do not share medicines prescribed for you with any other person.

Always take **MYLAN PANTOPRAZOLE** exactly as your doctor has instructed you.

You should check with your doctor or pharmacist if you are unsure.

If you have the impression that the effect of **MYLAN PANTOPRAZOLE** is too strong or too weak, talk to your doctor or pharmacist.

MYLAN PANTOPRAZOLE 20 mg and **MYLAN PANTOPRAZOLE 40 mg** should be swallowed whole with a little water either before or during breakfast. Your doctor will decide on the correct dose for you, depending on how much medicine is needed to treat your condition.

For duodenal and stomach ulcers:

One **MYLAN PANTOPRAZOLE 40 mg** tablet daily.

After consultation with your doctor the dosage may be doubled.

Your doctor will tell you how long to take your medicine. The treatment for stomach ulcers is usually between 4 and 8 weeks. The treatment period for duodenal ulcers is between 2

and 4 weeks.

Reflux oesophagitis:

One 40 mg of **MYLAN PANTOPRAZOLE** tablet daily.

Your doctor will tell you how long to take the medicine. The treatment period for reflux oesophagitis is usually between 4 and 8 weeks.

Zollinger-Ellison syndrome:

For the treatment of Zollinger-Ellison syndrome:

Two tablets of **MYLAN PANTOPRAZOLE 40 mg** per day (the recommended starting dose).

Take two tablets before breakfast. Your doctor may later adjust the dosage, depending on the amount of acid you produce.

Mild gastro-esophageal reflux disease (GERD):

One 20 mg of **MYLAN PANTOPRAZOLE** per day (the recommended dose).

A 4-week period is usually required for healing of mild GERD. Your doctor may recommend further long-term treatment.

If symptom control has not been achieved after four weeks of treatment with the prescribed daily dose, further investigation is recommended.

The recommended oral dose is one **MYLAN PANTOPRAZOLE 20 mg** tablet per day.

Elderly patients:

No dosage adjustment is necessary in the elderly.

Impaired renal and liver function:

No dosage adjustment is required in the presence of impaired renal function. A daily dose of 20 mg of **MYLAN PANTOPRAZOLE** should not be exceeded in patients with mild to moderate severe liver impairment.

If you take more MYLAN PANTOPRAZOLE than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take MYLAN PANTOPRAZOLE:

If you forgot to take a dose of **MYLAN PANTOPRAZOLE**, take it as soon as you remember. However, if it is almost time for your next dose, do not take the missed dose, take the next dose on time. Do not take a double dose to make up for forgotten individual doses.

5. POSSIBLE SIDE EFFECTS:

MYLAN PANTOPRAZOLE can have side effects.

Not all side effects reported for **MYLAN PANTOPRAZOLE** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **MYLAN PANTOPRAZOLE,** please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking **MYLAN PANTOPRAZOLE** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the face, lips, tongue or throat which may cause difficulty in swallowing or breathing.
- An extremely severe skin reaction with ulcers or blisters on the skin. This is known as

Stevens-Johnson syndrome.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **MYLAN PANTOPRAZOLE.**

You may need urgent medical attention or hospitalisation.

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

- Headache
- Stomach pain
- Diarrhoea or constipation
- Wind
- Dizziness
- Blurred vision
- Feeling or being sick
- Allergic itchy skin
- Dry mouth
- Joint pain
- Unusual bruising or bleeding of the skin
- Liver problems, dark urine, pale stools
- Nettle rash (hives)
- Difficulty passing urine, blood in the urine
- Raised liver enzymes in blood
- An increase in body temperature
- Feeling depressed
- Yellowing of the skin and whites of the eyes

- Muscle pain
- Swollen ankles
- Raised triglycerides (fats) in the blood

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF MYLAN PANTOPRAZOLE TABLETS:

KEEP OUT OF THE REACH OF CHILDREN.

Store at or below 30 °C. Keep container well closed.

Store in the original container.

Do not use after the expiry date stated on the bottle.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF MYLAN PANTOPRAZOLE TABLETS:

MYLAN PANTOPRAZOLE 20 mg and **MYLAN PANTOPRAZOLE 40 mg** tablets are available in white HDPE bottles or blister packs of 7, 14, 15, 28, 30, 50, 56, 60, 100 and 250 tablets.

8. IDENTIFICATION OF MYLAN PANTOPRAZOLE TABLETS:

MYLAN PANTOPRAZOLE 20 mg: Yellow to ocher, elongated enteric-coated tablet.

MYLAN PANTOPRAZOLE 40 mg: Pale yellow to ocher, elongated enteric-coated tablet.

9. REGISTRATION NUMBERS/REFERENCE NUMBERS:

MYLAN PANTOPRAZOLE 20 mg : 43/11.4.3/0843

MYLAN PANTOPRAZOLE 40 mg : 43/11.4.3/0844

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

Viatris South Africa (Pty) Ltd

4 Brewery Street,

Isando,

Johannesburg,

1609

11. DATE OF PUBLICATION:

25 November 2011