Each vial contains pantoprazole sodium sesquihydrate equivalent to 40 mg pantoprazole.

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

PANTOCID® 40 mg INJECTION

Lyophillised Powder for Injection

Pantoprazole sodium sesquihydrate equivalent to 40 mg pantoprazole

Sugar free

Read all of this leaflet carefully before you are given PANTOCID® 40 mg INJECTION

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

What is in this leaflet

1. WHAT PANTOCID® 40 MG INJECTION IS AND WHAT IT IS USED FOR

PANTOCID® 40 mg INJECTION contains pantoprazole which belongs to a group of medicines known as proton pump inhibitors.

PANTOCID® 40 mg INJECTION is used to treat certain conditions in which there is too much acid in the stomach. It is used to treat duodenal and gastric ulcers, reflux oesophagitis and Zollinger-Ellison Syndrome. **PANTOCID® 40 mg INJECTION** works by decreasing the amount of acid produced by the stomach.

2. PANTOCID® 40 mg INJECTION should not be administered to you:

- If you are hypersensitive (allergic) to pantoprazole or any of the other ingredients of **PANTOCID® 40 mg INJECTION**.

- If you have serious liver problems
- **PANTOCID® 40 mg INJECTION** should not be given to children.

Warnings and precautions

Tell your doctor or health care provider before being given **PANTOCID® 40 mg INJECTION:**

- You have liver problems. Your liver enzymes should be monitored during therapy. In the case of a rise in your liver enzymes, **PANTOCID® 40 mg INJECTION** should be discontinued.
- You have a gastric ulcer or a serious disease of your oesophagus (the tube that delivers food from your mouth to your stomach).
- You have been taking any acid-blocking medicines over a long period of time (i.e. longer than 3 years).
- Prolonged treatment with **PANTOCID® 40 mg INJECTION** may cause low serum magnesium levels with symptoms such as fatigue, dizziness, delirium and convulsions.
- Your doctor will administer **PANTOCID® 40 mg INJECTION** to you as it is to be used for a short period, your symptoms continue in spite of your treatment. Your doctor may decide that you need some tests to rule out malignant disease, because **PANTOCID® 40 mg INJECTION** also alleviates the symptoms of cancer and could cause a delay in diagnosing it.
- If you receive long-term treatment with **PANTOCID® 40 mg INJECTION**, you are at risk of fractures of the hip, wrist or spine.
- You have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis).
- You are due to have a specific blood test measuring Chromogranin A.

Other medicines and PANTOCID® 40 mg INJECTION:

Always tell your health care provider if you are taking any other medicines (this include complementary or traditional medicines).

- **PANTOCID® 40 mg INJECTION** may reduce the absorption of certain medicines used to treat fungal infections, such as ketoconazole and itraconazole.
- **PANTOCID® 40 mg INJECTION** may decrease the amount of atazanavir or nelfinavir, used to treat HIV infection.

- Medicines to thin your blood such as warfarin. **PANTOCID® 40 mg INJECTION** may alter the effect of these medicines so your doctor may monitor how well your blood clots.
- **PANTOCID® 40 mg INJECTION** may increase the levels of methotrexate (high doses used in the treatment of certain cancers) and possibly lead to methotrexate toxicities.
- Fluvoxamine (used to treat depression and other psychiatric diseases).
- Rifampicin (used to treat infections).
- St John's wort (*Hypericum perforatum*) (used to treat mild depression

PANTOCID® 40 mg INJECTION with food or drink

Food does not affect **PANTOCID® 40 mg INJECTION** function.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before receiving this medicine. Safety in pregnancy and breastfeeding has not been established.

Driving and using machinery:

PANTOCID® 40 mg INJECTION may cause dizziness and disturbances in vision (blurred vision). Do not drive a vehicle or operate machinery until you know how **PANTOCID® 40 mg INJECTION** will affect you.

3. HOW TO RECEIVE PANTOCID® 40 MG INJECTION

You will not be expected to give yourself **PANTOCID® 40 mg INJECTION.** It will be given to you by a person who is qualified to do so. Your doctor will decide on the suitable dose, based on your condition. The normal dose is 40 mg (one vial).

If you receive more PANTOCID® 40 mg INJECTION than you should:

Since a healthcare professional will administer **PANTOCID® 40 mg INJECTION**, he/she will control the dosage. However, in the event of an overdosage, your doctor will manage any symptoms of the overdosage.

4. POSSIBLE SIDE EFFECTS

PANTOCID® 40 mg INJECTION can have side effects. Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen while receiving this medicine, please consult your doctor, pharmacist or other health care professional for advice.

If any of the following happen, stop receiving **PANTOCID® 40 mg INJECTION** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side-effects. If you have them, you may have had a serious allergic reaction to **PANTOCID® 40 mg INJECTION**. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Side effects with an unknown frequency:

- Severe skin reactions, such as Stevens-Johnson syndrome, erythema multiforme or Lyell syndrome.
- Inflammation of the kidney (characterised by blood in the urine, fever, increased or decreased urine output, drowsiness, confusion, coma, nausea, vomiting).
- Yellowing of the skin and eyes (also called jaundice).
- Low levels of magnesium in your body with symptoms such as fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness or an increased heart rate.
- Increased risk for gastrointestinal infections, with accompanied diarrhoea.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor as soon as possible if you notice any of the following:

Side effects occurring frequently:

- Small growths (polyps) in the inner lining of the stomach.
- Pain at the site of the injection.

Side effects occurring less frequently:

- Blood disorders such as leukopenia (a low white blood cell count) or thrombocytopenia (decreased number of platelets in the blood).

- Increased liver enzymes, triglycerides (a type of fat found in your blood) or body temperature.
- Headache.
- Abdominal pain, diarrhoea, constipation, flatulence.
- Feeling depressed, sleep disorders, disorientation.
- Dizziness, blurred vision.
- Distortion or complete lack of your sense of taste.
- Changes in your weight.
- Dry mouth.
- Bloating, swelling of the abdomen.
- Skin rash with red, raised itchy bumps, hives.
- Swelling of the hands, arms, legs and feet.
- Raised body temperature.
- Nausea (feeling sick), vomiting (being sick), dry mouth.
- Muscle or joint pain.
- Enlargement of breasts in men or boys (Gynecomastia).
- Loss of energy or feeling week.
- Feeling tired.
- a general feeling of discomfort, illness, or unease whose exact cause is difficult to identify.

Side effects with an unknown frequency:

- A sudden loss of vision.
- Confusion, seeing or hearing things that are not there.
- Pins and needles, burning sensation or numbness.
- Sensitivity of your skin when exposed to sunlight.

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

Reporting of side effects

If you get side effects, talk to your doctor. You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reaction Reporting Form"** found online under SAHPRA's publications: https:www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help providing information on the safety of **PANTOCID® 40 mg INJECTION.**

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5. HOW TO STORE PANTOCID® 40 MG INJECTION

Store at or below 25 °C, protect from light.

Discard any unused solution.

Do not receive **PANTOCID® 40 mg INJECTION** after the expiry date stated on the label.

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

STORE ALL MEDICINES OUT OF THE REACH OF CHILDREN.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What PANTOCID® 40 mg INJECTION contains:

Active ingredient: Pantoprazole sodium sesquihydrate.

Inactive ingredients: Water for injection, nitrogen.

What PANTOCID 40 MG INJECTION looks like and contents of the pack

PANTOCID® 40 mg INJECTION: A white to off-white lyophilised cake in a 10 mL colourless glass vial for intravenous injection.

The reconstituted solution is a clear yellowish solution.

One, five or ten vials are packed into an outer carton.

Holder of the Certificate of Registration:

Ranbaxy Pharmaceuticals (Pty) Ltd

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Johannesburg 1724

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Registration number

PANTOCID® 40 mg INJECTION: A40/11.4.3/0072

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Namibia:

PANTOCID® 40 mg INJECTION: NS2 Reg. no.: 06/11.4.3/0332