PANTOCID 20 / 40
Ranbaxy Pharmaceuticals (Pty) Ltd

Each tablet contains pantoprazole sodium sesquihydrate equivalent to 20,0 mg / 40 mg pantoprazole.

Patient Information Leaflet

Scheduling Status: S4

PANTOCID 20® enteric-coated tablets

Pantoprazole sodium sesquihydrate equivalent to 20 mg pantoprazole

Contains: 2,5 mg lactose anhydrous and 22,75 mg mannitol

PANTOCID 40® enteric-coated tablets

Pantoprazole sodium sesquihydrate equivalent to 40 mg pantoprazole

Contains: 5,0 mg lactose anhydrous and 45,5 mg mannitol

Read all of this leaflet carefully before you start taking PANTOCID®

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

What is in this leaflet

1. WHAT PANTOCID® IS AND WHAT IT IS USED FOR

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

PANTOCID® 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. It is indicated for symptomatic improvement (e.g. heartburn, contents of the stomach which washes back into the oesophagus, pain on swallowing) and healing of mild gastro-oesophageal reflux disease. **PANTOCID®** is indicated for the prevention of gastroduodenal lesions, heartburn and indigestion symptoms caused by nonselective non-steroidal anti-inflammatory drugs (NSAID's), i.e medicines other than cortisone used to treat pain and inflammation. **PANTOCID®** works by decreasing the amount of acid produced by the stomach.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE PANTOCID®

Do not take PANTOCID®:

- If you are hypersensitive (allergic) to pantoprazole or any of the other ingredients of **PANTOCID®**.
- If you have serious liver problems
- **PANTOCID®** should not be given to children.
- If you are taking a medicine called atazanavir (an anti-HIV medicine).

Warnings and precautions

Special care should be taken with **PANTOCID®**

- If you have been diagnosed with severe liver impairment
- if you have impaired kidney function
- if you are taking warfarin, a medicine that reduces the risk of blood clotting
- if you are taking tablets containing ketoconazole, used to treat fungal infections of the skin and nails. This is because **PANTOCID®** may increase or decrease the effect of ketoconazole by altering the amount that gets in your body.
- if you are taking HIV protease inhibitors such as atazanavir (for the treatment of HIV-infection) at the same time as **PANTOCID®,** ask your doctor for specific advice**.**
- if you have a history of a Vitamin B12 deficiency and receive long-term treatment (e.g. longer than 3 years) with **PANTOCID®**. **PANTOCID®** may lead to a reduced absorption of Vitamin B12.

- if you are currently being treated or have a history of any malignancies in the stomach area, or ~~if~~ you think you have signs of stomach cancer. These include persistent weight loss, dark stools, loss of appetite, feeling full or a lump in your stomach.
- if you experience severe and/or persistent diarrhoea, as **PANTOCID®** has been associated with a small increase in diarrhoea caused by an infection (Clostridium difficile) in your intestines. Call your doctor right away if you have watery stool, stomach pain, and fever that does not go away.
- if you need to take medicines called NSAIDs continuously and receive **PANTOCID®** because you have an increased risk of developing stomach and intestinal complications.
- if you are over 50 years of age or when you take **PANTOCID®** for a long period of time (more than one year) or in high doses, it may cause a low magnesium level in the body and cause an increase in risk of bone fractures in the hip, wrist or spine
- if you have or had a bone fracture in the hip, wrist or spine due to low magnesium
- if you have ever had a skin reaction after treatment with a medicine similar to **PANTOCID®** 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 **PANTOCID®**. Remember to also mention any other ill-effects like pain in your joints
- if you take **PANTOCID®** 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
- if you are on pantoprazole, as in **PANTOCID®**, 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 there is a decrease in the amount that you urinate or if you have blood in your urine.

- if you are due to have a specific blood test (Chromogranin A) **PANTOCID®** treatment should be stopped for at least 5 days before Chromogranin A (CgA) measurements are taken and may require a further test 14 days after stopping therapy with **PANTOCID®**.

Other medicines and PANTOCID®:

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

- **PANTOCID®** may reduce the absorption of certain medicines used to treat fungal infections, such as ketoconazole and itraconazole.
- **PANTOCID®** may decrease the amount of atazanavir or nelfinavir, used to treat HIV infection. You should not use **PANTOCID®** concurrently with atazanavir.
- Medicines to thin your blood such as warfarin. **PANTOCID®** may alter the effect of these medicines so your doctor may monitor how well your blood clots.
- **PANTOCID®** 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) – if you are taking fluvoxamine your doctor may reduce the dose
- St John's wort (Hypericum perforatum) (used to treat mild depression)
- the active ingredient, pantoprazole, is metabolised by certain liver enzymes, which may interact with other medicines or compounds which are also metabolised by these enzymes.

PANTOCID® with food or drink

You must take your tablet before or during your morning meal. Food does not affect the tablet's function.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before using **PANTOCID®**.

Do not take **PANTOCID**® if you are pregnant or breastfeeding your baby, safety in pregnancy and breastfeeding has not been established.

Driving and using machinery:

PANTOCID® may cause fatigue or dizziness. It is not always possible to predict to what extent **PANTOCID**® may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which **PANTOCID**® affects them **PANTOCID**® contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

3. HOW TO TAKE PANTOCID®

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

Always take **PANTOCID**® exactly as described in this leaflet or as your doctor or pharmacist have told you. You should check with your doctor if you are unsure.

PANTOCID® should be swallowed whole with a little water in the morning either before or during breakfast. Do not crush, split or chew the tablet.

The usual dose is:

Duodenal ulcer: One tablet of **PANTOCID® 40** once daily in the morning for 2 to 4 weeks. Your doctor may combine your treatment with antibiotics if *H. pylori* infection is present.

Stomach ulcer: One tablet of **PANTOCID® 40** once daily in the morning for 4 to 8 weeks.

Reflux esophagitis: One tablet of **PANTOCID® 40** once daily in the morning for 4 to 8 weeks.

Zollinger-Ellison Syndrome: You should start treatment with a daily dose of 80 mg of **PANTOCID**® (2 tablets of **PANTOCID**® 40).

Your doctor can increase the dose above 80 mg.

Mild gastro-esophageal reflux disease (GERD): One tablet of **PANTOCID 20®** in the morning for 4 weeks. Your doctor will decide if you should continue treatment for another 4 weeks.

Long-term management and prevention of relapse in GERD: A maintenance dose of one **PANTOCID®** **20** tablet per day is recommended. Your doctor may increase the dose to **40 mg** if your GERD symptoms worsen. After healing, you can continue with the **20 mg** dosage regimen.

Children:

Safety and efficacy in children has not been established.

Your doctor will tell you how long your treatment with **PANTOCID®** will last. Do not stop treatment early because your condition may worsen.

If you have the impression that the effect of **PANTOCID®** is too strong or too weak, tell your doctor or pharmacist.

If you take more PANTOCID® than you should:

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

Take this leaflet and any remaining tablets with you, so that the doctor knows what you have taken.

If you forget to take PANTOCID®:

If you missed a dose, take it as soon as you remember. If it is almost time for your next dose, skip the missed dose and continue to take the tablet at the usual time.

Do not take a double dose to make up for the forgotten individual doses.

If you have trouble remembering when to use your medicine, ask your pharmacist for some hints.

If you stop taking PANTOCID®:

Take **PANTOCID®** tablets for the full time of treatment, even if you begin to feel better. Do not stop treatment early because your condition may worsen.

4. POSSIBLE SIDE EFFECTS

PANTOCID® can have side effects.

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

If any of the following happen, stop taking **PANTOCID®** 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®**. 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:

Less frequent:

- Yellowing of the skin and whites of the eyes, also called jaundice.
- Skin reactions (including skin rashes, hives, inflammation or swelling, blistering, peeling, loosening of skin, red skin lesions, often with a purple centre, sores or ulcers).
- Blood disorders associated with sore throat, fever or chills; cough or hoarseness; lower back or side pain; painful or difficult urination; unusual bleeding or bruising; black, tarry stools; blood in urine or stools; pinpoint red spots on skin.
- blurred vision.

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

Tell your doctor if you notice any of the following:

Frequent:

Headache, abdominal pain, diarrhoea, gas, nausea/vomiting, constipation, skin rashes.

Less frequent:

Dizziness, sleepiness, unusual tiredness or weakness, fatigue, malaise (feeling bad), swelling of the hands and feet, trouble in sleeping, confusion, agitation, hallucinations (seeing, hearing, or feelings things that are not there), depression, aggression, bronchospasm (suddenly feeling wheezy or short of breath), nausea and/or vomiting, stomach pain and discomfort, dry mouth, taste disturbances, sores in the mouth, blurred vision, hair loss, other skin conditions, increased sweating, increased body temperature, high concentration of fatty products in the blood, impotence, enlarged breasts in men, vertigo (sense of constant movement of self or surroundings), joint or muscle pain, fracture of the hip, wrist or spine. Changes in blood tests that check how the liver is working, blood problems such as a reduced number of white blood cells or platelets, low levels of sodium in the blood, an infection called “thrush” which can affect the gut, severe kidney problems.

Frequency unknown:

Low magnesium or calcium levels in your body (see Take special care with **PANTOCID®**), severe liver problems leading to liver failure and inflammation of the brain.

You may also get inflammation in the large bowel that causes severe diarrhoea characterised by watery stools, stomach pain, fever (Clostridium difficile associated diarrhoea).

Feeling of tingling, prickling, pins and needles, burning sensation or numbness. Hallucination or confusion.

Muscle spasm as a consequence of electrolyte disturbance

A type of kidney problem (acute interstitial nephritis). Some people who take proton pump inhibitor (PPI) medicines, including **PANTOCID®**, may develop a kidney problem called acute interstitial nephritis that can happen at any time during treatment with PPI medicines. Call your doctor right away if you have a decrease in the amount that you usually urinate or if you have blood in your urine.

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help providing information on the safety of **PANTOCID®.**

Suspected side effects can also be reported directly to the HCR via email:

pharmacovigilance.africasme@sunpharma.com or tel: +27(0) 12 643 2000

5. HOW TO STORE PANTOCID®

Store at or below 25 °C, protected from moisture.

Keep the bottle tightly closed or do not remove the blisters from the carton until required for use.

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.

Do not store in bathrooms in order to protect from moisture.

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

Return all unused medicine to your pharmacist.

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

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What PANTOCID® contains:

Active ingredient: Pantoprazole sodium sesquihydrate.

Inactive ingredients: Calcium stearate, crospovidone, ferric oxide (yellow), hypromellose, lactose anhydrous, mannitol, methacrylic acid copolymer type C, Opacode black, polyethylene glycol, Povidone K90, sodium carbonate anhydrous, talcum, titanium dioxide, triethyl citrate.

Contains sugar (lactose).

What PANTOCID® looks like and contents of the pack

PANTOCID® 20: Yellow, circular, biconvex, coated tablet imprinted “144” on one side and plain on the other side.

PANTOCID® 40: Yellow, circular, biconvex, coated tablet imprinted “124” on one side and plain on other side.

HDPE Bottle pack

PANTOCID® 20/40 may be presented in either blister packs or white round HDPE bottles packs. Not all pack types may be marketed simultaneously.

PANTOCID® 20 is available in pack sizes of 7, 14, 30 and 90 packed in white smooth round HDPE containers.

PANTOCID® 40 is available in pack sizes of 14, 30, 90 and 1 000 packed in white smooth round HDPE containers.

Blister pack

3 blisters of 10 tablets packaged in the Aluminum/Aluminum blister consists of triple layer laminate made up of 25 OPA/45 AL/ 60 PVC forming material film and Push through aluminum foil with 6-8 GSM heat seal lacquer lidding foil.

Holder of the Certificate of Registration:

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This leaflet was last revised in

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Registration number

PANTOCID® 20: 41/11.4.3/0787

PANTOCID® 40: A40/11.4.3/0482

Access to the corresponding PIL translation:

The PIL is available in one other language (Afrikaans), a copy is accessible on the company website:

https://sunpharma.com/south-africa-products/