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
2. What you need to know before you take **PANTOCID®**
3. How to take **PANTOCID®**
4. Possible side effects
5. How to store **PANTOCID®**
6. Contents of the pack and other information

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

18 March 2026

PANTOCID 20 / 40 **Ranbaxy Pharmaceuticals (Pty) Ltd**	Each tablet contains pantoprazole sodium sesquihydrate equivalent to 20,0 mg / 40 mg pantoprazole.

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/

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

PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS: S4

PANTOCID 20® entries-bedekte tablette

Natriumpantoprasool-seskwihidraat gelykstaande aan 20 mg pantoprasool

Bevat: 2,5 mg anhidriese laktose en 22,75 mg mannitol

PANTOCID 40® entries-bedekte tablette

Natriumpantoprasool-seskwihidraat gelykstaande aan 40 mg pantoprasool

Bevat: 5,0 mg anhidriese laktose en 45,5 mg mannitol

Lees die hele inligtingstuk noukeurig deur voordat jy begin om PANTOCID® te neem

- Hou hierdie inligtingstuk. Jy sal dit moontlik weer moet lees.
- Vra asseblief jou dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer as jy verdere vrae het.
- Hierdie medisyne is vir jou persoonlik voorgeskryf en jy moenie jou medisyne met enige ander persoon deel nie. Dit kan skadelik vir hulle wees, selfs as hulle simptome soortgelyk aan joune is.

Wat is in hierdie inligtingstuk

1. Wat **PANTOCID®** is en waarvoor dit gebruik word
2. Wat jy moet weet voordat jy **PANTOCID®** neem
3. Hoe om **PANTOCID®** te neem
4. Moontlike newe-effekte
5. Hoe om **PANTOCID®** te bewaar
6. Inhoud van die verpakking en ander inligting

1. WAT PANTOCID® IS EN WAARVOOR DIT GEBRUIK WORD

PANTOCID® bevat pantoprasool wat aan ‘n groep medisyne behoort wat bekend staan as protonpomp-remmers.

PANTOCID® word gebruik om sekere toestande te behandel waar daar te veel suur in die maag is. Dit word gebruik om duodenale en maagsere, refluks-esofagitis en Zollinger-Ellison-sindroom te behandel. Dit word aangedui vir simptomatiese verligting (bv. sooibrand, wanneer die maaginhoud opstoot in die slukderm, pyn wanneer gesluk word) en genesing van ligte gastro-esofageale reflukssiekte. **PANTOCID®** word aangedui vir die voorkoming van gastro-duodenale letsels, sooibrand en slegte spysverteringsimptome wat veroorsaak word deur nie-selektiewe nie-steroïdale anti-inflammatoriese geneesmiddels (NSAIM's), d.i. ander medisune as kortisoon wat gebruik word om pyn en inflammasie te behandel. **PANTOCID®** werk deur die hoeveelheid suur wat deur die maag geproduseer word, te verlaag.

2. WAT JY MOET WEET VOORDAT JY PANTOCID® NEEM

Moenie PANTOCID® neem nie:

- As jy hipersensitief (allergies) is vir pantoprasool of vir enige van die ander bestanddele van **PANTOCID®**.
- As jy ernstige lewerprobleme het.
- **PANTOCID®** moet nie aan kinders toegedien word nie.
- As jy medisyne gebruik wat bekend staan as atasanavir ('n anti-MIV medisyne).

Waarskuwings en voorsorgmaatreëls

Spesiale voorsorg moet met **PANTOCID®** getref word

- as jy gediagnoseer is met ernstige lewerinkorting
- as jy ingekorte nierfunksie het
- as jy warfarien gebruik, 'n medisyne wat die risiko van bloedstolling verlaag
- as jy tablette neem wat ketokonasool bevat, gebruik om fungusinfeksies van die vel en naels te behandel. Dit is omdat **PANTOCID®** die effek van ketokonasool kan verhoog of verlaag deur die hoeveelheid wat in jou liggaaam opgeneem word, te verander.
- as jy MIV-protease-remmers soos atasanavir (vir die behandeling van MIV-infeksie) op dieselfde tyd as **PANTOCID®** neem**,** moet jy jou dokter vir spesifieke advies raadpleeg.
- as jy 'n geskiedenis van vitamien B_{12}-tekort het en langtermynbehandeling (bv. langer as 3 jaar) met **PANTOCID®** ontvang. **PANTOCID®** kan tot 'n verlaagde absorpsie van vitamien B_{12} lei.

- as jy tans behandel word of ‘n geskiedenis van kwaadaardighede in die maagarea het, of jy dink dat jy tekens van maagkanker het. Hierdie sluit aanhoudende gewigsverlies, donker stoelgang, verlies aan aptyt, ‘n volgevoel of ‘n knop in jou maag in.
- as jy erge en/of aanhoudende diarree ervaar, aangesien **PANTOCID®** geassosieer word met ‘n klein toename in diarree veroorsaak deur ‘n infeksie (*Clostridium difficile*) in jou ingewande. Kontak jou dokter dadelik as jy ‘n waterige stoelgang, maagpyn en koors ervaar wat nie wil verdwyn nie.
- as jy ander medisyne wat NSIAM’s genoem word aanhoudend moet gebruik en **PANTOCID®** ontvang omdat jy ‘n verhoogde risiko het om maag- en ingewandskomplikasies te ontwikkel
- as jy ouer as 50 jaar oud is of wanneer jy **PANTOCID®** vir ‘n lang tydperk (meer as een jaar) of in hoë dosisse neem, kan dit ‘n lae magnesiumvlak in die liggaam veroorsaak en ‘n toename in die risiko van beenfrakture in die heupe, gewrigte of ruggraat veroorsaak
- as jy ‘n beenfraktuur in die heup, gewrig of ruggraat het of gehad het
- as jy ‘n velreaksie gehad het ná behandeling met ‘n medisyne wat soortgelyk is aan **PANTOCID®** wat maagsuur verlaag
- as jy ‘n uitslag op jou vel ontwikkel, veral op areas wat aan die son blootgestel is, moet jy jou dokter so gou as moontlik inlig, aangesien dit vir jou nodig mag wees om jou behandeling met **PANTOCID®** te staak. Onthou ook om enige ander ongewenste effekte, soos pyn in jou gewrigte, te noem
- as jy **PANTOCID®** op ‘n langtermyn basis (langer as een jaar) gebruik, sal jou dokter jou waarskynlik onder gereelde toesig hou. Jy moet enige nuwe en uitsonderlike simptome en omstandigheide aanmeld wanneer jy jou dokter sien
- as jy pantoprasool, soos in P**ANTOCID®**, vir meer as drie maande neem, is dit moontlik dat die vlakke van magnesium in jou bloed kan daal. Lae vlakke van magnesium kan as moegheid, onwillekeurige spiersametrekkings, disoriëntasie, konvulsies, duiseligheid of verhoogde hartritme waargeneem word. Indien jy enige van hierdie simptome ervaar, moet jy asseblief jou dokter onmiddellik inlig. Lae vlakke van magnesium kan ook tot ‘n afname in kalium- of kalsiumvlakke in die bloed lei. Jou dokter kan besluit om gereelde bloedtoetse uit te voer om die vlakke van magnesium in jou bloed te monitor.
- as daar ‘n afname in die hoeveelheid wat jy urineer is of as jy bloed in jou urine het

- as jy ‘n spesifieke bloedtoets (Chromogranin A) moet ondergaan, moet **PANTOCID®**-behandeling vir ten minste 5 dae vóór Chromogranin A (CgA) bepalings gedoen word, gestaak word en mag ‘n verdere toets 14 dae nadat terapie met **PANTOCID®** gestaak is, nodig wees.

Ander medisyne en PANTOCID®:

Lig jou gesondheidsorgverskaffer altyd in as jy ander medisyne gebruik. (Dit sluit aanvullende of tradisionele medisyne in).

- **PANTOCID®** kan die absorpsie van sekere medisyne wat gebruik word om fungusinfeksies te behandel, soos ketokonasool en itrakonasool, verlaag.
- **PANTOCID®** kan die hoeveelheid van atasanavir of nelfinavir wat gebruik word om MIV-infeksie te behandel, verlaag. Jy moenie **PANTOCID®** gelyktydig met atasanavir neem nie.
- Medisyne wat jou bloed verdun, soos warfarien. **PANTOCID®** kan die effek van hierdie medisyne verander Jou dokter sal monitor hoe goed jou bloed sal stol.
- **PANTOCID®** kan die vlakke van metotreksaat verhoog (hoë dosisse word gebruik in die behandeling van sekere kanker) en moontlik lei tot metotreksaat-vergiftiging
- Fluvoksamien (wat gebruik word om depressie en ander psigiatriese siektes te behandel)
  – as jy fluvoksamien neem, mag jou dokter die dosis verlaag
- Johanneskruid (Hypericum perforatum) (wat gebruik word om ligte depressie te behandel).

- Die aktiewe bestanddeel, pantoprasool, word deur sekere lewerensieme gemetaboliseer wat kan wisselwerk met ander medisyne of verbindings wat ook deur hierdie ensieme gemetaboliseer word.

PANTOCID® saam met voedsel of drinkgoed

Jy moet jou tablet vóór of tydens jou ontbyt neem. Voedsel affekteer nie die tablet se werking nie.

Swangerskap en borsvoeding:

As jy swanger is of jou baba borsvoed, dink dat jy swanger mag wees of as jy beplan om 'n baba te hê, moet jy asseblief jou dokter, apteker of ander gesondheidsorgverskaffer raadpleeg vir advies voordat jy **PANTOCID®** gebruik.

Moenie **PANTOCID®** neem as jy swanger is of jou baba borsvoed nie, aangesien die veiligheid nog nie vasgestel is nie.

Bestuur en gebruik van masjinerie:

PANTOCID® kan moegheid of duiseligheid veroorsaak. Dit is nie altyd moontlik om te voorspel tot watter mate **PANTOCID®** met die daaglikse aktiwiteite van ‘n pasiënt kan inmeng nie. Pasiënte moet seker maak dat hulle nie betrokke raak in die bogenoemde aktiwiteite, totdat hulle kan bepaal tot watter mate **PANTOCID®** hulle affekteer, nie. **PANTOCID®** bevat laktose wat ‘n effek op die beheer van jou bloedglukose kan hê as jy diabetes mellitus het.

3. HOE OM PANTOCID® TE NEEM

Moenie medisyne wat vir jou voorgeskryf is, met enige ander persoon deel nie.

Neem **PANTOCID®** altyd presies soos wat dit in hierdie inligtingstuk aangedui is of soos wat jou dokter of apteker dit voorgeskryf het. Jy moet met jou dokter kontroleer as jy onseker is.

PANTOCID® moet heel met ‘n bietjie water in die oggend óf voor ontbyt óf met ontbyt ingesluk word. Moenie die tablet fynmaak, verdeel of kou nie.

Die normale dosis is:

Duodenale seer: Een **PANTOCID® 40** tablet een keer per dag in die oggend vir 2 tot 4 weke. Jou dokter kan jou behandeling kombineer met antibiotika as *H. pylori*-infeksie teenwoordig is.

Maagseer: Een **PANTOCID® 40** tablet een keer per dag in die oggend vir 4 tot 8 weke.

Refluks-esofagitis: Een **PANTOCID® 40** tablet een keer per dag in die oggend vir 4 tot 8 weke.

Zollinger-Ellison se sindroom: Jy moet behandeling begin met ‘n daaglikse dosis van 80 mg **PANTOCID®** (2 **PANTOCID®** 40 tablette).

Jou dokter kan die dosis bo 80 mg verhoog.

Ligte gastro-esofageale reflukssiekte (GERD): Een **PANTOCID® 20** tablet een keer per dag in die oggend vir 4 weke. Jou dokter sal besluit of jy vir nog 4 weke moet voortgaan met die behandeling.

Langtermyn instandhouding en voorkoming van terugval in GERD: 'n Instandhoudingsdosis van een **PANTOCID® 20** tablet per dag word aanbeveel. Jou dokter kan die dosis verhoog tot **40 mg** as jou GERD simptome vererger. Nadat jy gesond geword het, kan jy voortgaan met die **20 mg** dosisregimen.

Kinders:

Veiligheid en doeltreffendheid is nie by kinders vasgestel nie.

Jou dokter sal jou inlig oor hoe lank jou behandeling met **PANTOCID®** sal duur. Moenie vroeg met die behandeling ophou nie omdat jou toestand mag versleg. Lig jou dokter of apteker in as jy onder die indruk is dat die effek van **PANTOCID®** te sterk of te swak is.

As jy meer PANTOCID® geneem het as wat jy behoort te neem:

Raadpleeg jou dokter of apteker in die geval van oordosering. Indien nie een van hulle beskikbaar is nie, soek hulp by die naaste hospitaal of gifbeheersentrum.

Neem hierdie inligtingstuk en enige oorblywende tablette saam met jou sodat die dokter kan weet wat jy geneem het.

As jy vergeet het om PANTOCID® te neem:

As jy 'n dosis oorgeslaan het, neem dit so gou as wat jy onthou. Indien dit amper tyd is vir jou volgende dosis, slaan die dosis oor wat jy vergeet het en gaan voort om die tablet op die normale tyd te neem.

Moenie 'n dubbele dosis neem om te vergoed vir die individuele dosisse wat jy vergeet het nie.

As dit vir jou moeilik is om te onthou wanneer om jou medisyne te neem, vra jou apteker vir wenke om jou daarmee te help.

As jy ophou om PANTOCID® te neem:

Neem **PANTOCID®** tablette vir die volle tydperk van behandeling, selfs as jy beter begin voel. Moenie vroeg met die behandeling ophou nie, omdat jou toestand kan versleg.

4. MOONTLIKE NEWE-EFFEKTE

PANTOCID® kan newe-effekte hê.

Nie alle newe-effekte wat vir hierdie medisyne aangemeld word, is in hierdie inligtingstuk opgeneem nie. Indien jou algemene gesondheid versleg terwyl jy hierdie medisyne neem, moet jy asseblief jou dokter, apteker of gesondheidsorgverskaffer raadpleeg vir advies.

Indien enige van die volgende gebeur, staak die gebruik van **PANTOCID®** en lig jou dokter onmiddellik in of gaan na die noodgevalle-afdeling by jou naaste hospitaal:

- swelling van die hande, voete, enkels, gesig, lippe, en mond, of keel, wat probleme met sluk of asemhaling kan veroorsaak,
- uitslag of gejeuk,
- floute.

Hierdie is almal baie ernstige newe-effekte. As jy bogenoemde ervaar, kon jy ‘n ernstige allergiese reaksie teen **PANTOCID®** gehad het. Jy mag dringende mediese aandag of hospitalisasie benodig.

Lig jou dokter onmiddellik in of gaan na die noodgevalle-afdeling by jou naaste hospitaal as jy enige van die volgende opmerk:

Minder algemeen:

- Vergeling van die vel en wit van die oë, ook geelsug genoem.
- Velreaksies (insluitend veluitslag, galbulte, inflammasie of swelling, blasievorming, afskilfering, losraak van die vel, rooi velletsels, dikwels met ‘n pers kern, sere of swere).
- Bloedversteurings geassosieer met seerkeel, koors of koue rillings; hoes of heesheid; laer rug-of sypyn, pynlike of moeilike urinering; ongewone bloeding of kneusing; swart, teeragtige stoelgang; bloed in die urine of stoelgang; speldepunt rooi kolletjies op die vel.
- Dowwe visie.

Hierdie is almal ernstige newe-effekte. Jy mag dringende mediese aandag benodig.

Lig jou dokter in indien jy enige van die volgende opmerk:

Dikwels:

Hoofpyn, abdominale pyn, diarree, winderigheid, naarheid/braking, hardlywigheid, veluitslag.

Minder dikwels:

Duiseligheid, slaperigheid, ongewone moegheid of swakheid, uitputting, malaise (voel sleg), swelling van die hande en voete, sukkel om te slaap, verwarring, agitasie, hallusinasies (sien, hoor of voel dinge wat nie bestaan nie), depressie, aggressie, brongospasma (voel skielike hyging of kortasemigheid), naarheid en/of braking, maagpyn en ongemak, droë mond, smaakversteurings, sere in die mond, dowwe visie, haarverlies, ander veltoestande, verhoogde sweet, verhoogde liggaamstemperatuur, hoë konsentrasie van vetterige produkte in die bloed, impotensie, vergrote borste by mans, vertigo (gevoel van konstante beweging van jouself of die omgewing), gewrigs- of spierpyn, fraktuur van die heup, gewrig of ruggraat. Veranderinge in bloedtoetse wat nagaan hoe die lewer funksioneer, bloedprobleme soos ‘n verlaagde aantal witbloedselle of plaatjies, lae vlakke van natrium in die bloed, ‘n infeksie wat ‘sproei’ genoem word wat die ingewande kan affekteer, ernstige nierprobleme.

Voorkoms onbekend:

Lae magnesium of kalsiumvlakke in jou liggaam (sien Tref spesiale voorsorg met **PANTOCID®**), ernstige lewerprobleme wat tot lewerversaking en inflammasie van die brein lei.

Jy kan ook inflammasie in die dikderm kry wat erge diarree veroorsaak gekenmerk deur waterige stoelgange, maagpyn en koors *(Clostridium difficile* geassosieerde diarree).

Gevoel van tinteling, prikkeling, naalde en spelde, branderige sensasie of gevoelloosheid. Hallusinasie of verwarring. Spierspasma as ‘n gevolg van elektrolietversteuring.

‘n Soort nierprobleem (akute interstisiële nefritis). Sommige persone wat protonpompinhibeerder (PPI) medisyne, insluitend **PANTOCID®** gebruik, kan ‘n nierprobleem wat akute interstisiële nefritis genoem word, ontwikkel wat op enige tydstip kan gebeur gedurende behandeling met PPI-medisyne. Lig jou dokter dadelik in as jy ‘n afname het in die hoeveelheid wat jy normaalweg urineer of as jy bloed in jou urine het.

Lig asseblief jou dokter of apteker in indien jy enige newe-effek opmerk wat nie in hierdie inligtingstuk genoem word nie.

Aanmelding van newe-effekte

Praat met jou dokter as jy newe-effekte kry. Jy kan ook newe-effekte by SAHPRA aanmeld *via* die MED Safety toepassing (MedSAHPRA) en eReporting platform (who-umc.org) wat aanlyn beskikbaar is op SAHPRA se webwef. Deur newe-effekte aan te meld, kan jy meer inligting oor die veiligheid van **PANTOCID®** verskaf**.**

Vermoedelike newe-effekte kan ook direk by die houer van die registrastiesertifikaat aangemeld word *via* e-pos: pharmacovigilance.africasme@sunpharma.com of tel: +27(0) 12 643 2000

5. HOE OM PANTOCID® TE BEWAAR

Bewaar by of onder 25 °C, beskerm teen vog.

Hou die bottle dig toe en moenie die stulpstroke uit die karton verwyder tot benodig vir gebruik nie.

HOU BUITE DIE BEREIK EN SIG VAN KINDERS.

Moenie in die badkamer bewaar nie om tablette teen vog te beskerm.

Moenie ná die vervaldatum soos op die etiket aangedui, gebruik nie.

Bring alle ongebruikte medisyne terug na jou apteker toe.

Moenie van ongebruikte medisyne in dreinerering- of rioleringstelsel (bv. toilette) ontslae raak nie.

6. INHOUD VAN DIE VERPAKKING EN ANDER INLIGTING

Wat PANTOCID® bevat:

Aktiewe bestanddeel: Natriumpantoprasool-seskwihidraat.

Onaktiewe bestanddele: Kalsiumstearaat, krospovidoon, ysteroksied (geel), hipromellose, anhidriese laktose, mannitol, metakriliese suur ko-polimeer tipe C, Opacode swart, poliëtileenglikool, Povidoon K90, anhidriese natriumkarbonaat, talk, titaandioksied, triëtielsitraat.

Bevat suiker (laktose).

Hoe PANTOCID® lyk en inhoud van die verpakking

PANTOCID® 20: Geel, ronde, bikonvekse, bedekte tablet gedruk met 144” op die een kant en skoon op die ander kant.

PANTOCID® 40: Geel, ronde, bikonvekse, bedekte tablet gedruk met “124” op die een kant en skoon op die ander kant.

HDPE-bottelverpakking

PANTOCID® 20/40 kan óf in stulpstrookverpakking óf in wit, ronde HDPE-bottelverpakking aangebied word. Nie alle verpakkingstipes word noodwendig gelyktydig bemark nie.

PANTOCID® 20 is beskikbaar in pakgroottes van 7, 14, 30 en 90 verpak in wit, gladde, ronde HDPE-houers.

PANTOCID® 40 is beskikbaar in pakgroottes van 14, 30, 90 en 1 000 verpak in wit, gladde, ronde HDPE-houers.

Stulpverpakking

3 stulpstroke van 10 tablette word verpak in die Aluminium/Aluminium-stulpstrook bestaande uit ‘n drielagige laminaat wat saamgestel is uit 25 OPA/45 AL/ 60 PVC vormende materiaalfilm en deurdrukbare aluminiumfoelie met 6-8 GSM hitteseëllak-bedekkingsfoelie.

Houer van die Registrasiesertifikaat

Ranbaxy Pharmaceuticals (Pty) Ltd

Lautreweg 14,

Stormill Uitbreiding 1,

Roodepoort

Johannesburg 1724

Tel no.: +27(0) 12 643 2000

Hierdie inligtingstuk was laas hersien op

18 March 2026

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

Registrasienommers

PANTOCID® 20: 41/11.4.3/0787

PANTOCID® 40: A40/11.4.3/0482