PANTOCID 20 / 40
Ranbaxy Pharmaceuticals (Pty) Ltd

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

PROFESSIONAL INFORMATION

SCHEDULING STATUS

S4

1. NAME OF THE MEDICINE

PANTOCID® 20 enteric coated tablets

PANTOCID® 40 enteric coated tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

PANTOCID® 20

Each enteric coated tablet contains pantoprazole sodium sesquihydrate equivalent to 20 mg pantoprazole.

Contains 2,5 mg lactose anhydrous and 22,75 mg mannitol per tablet

PANTOCID® 40

Each enteric tablet contains pantoprazole sodium sesquihydrate equivalent to 40 mg pantoprazole

Contains 5 mg lactose anhydrous and 45,5 mg mannitol per tablet

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Enteric coated tablets.

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.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

PANTOCID® 40 is indicated for the short-term treatment of duodenal ulcer, gastric ulcer and reflux oesophagitis. If the duodenal ulcer has been demonstrated to be associated with *Helicobacter pylori* infection. **PANTOCID® 40** used in combination with appropriate antibiotics may be useful.

PANTOCID® 40 is indicated for the treatment of Zollinger-Ellison syndrome.

PANTOCID® 20 is indicated for the symptomatic improvement (e.g. heartburn, acid regurgitation, pain on swallowing) and healing of mild gastro-esophageal reflux disease (GERD).

In patients with healed reflux disease, recurring symptoms can be controlled using an on-demand regimen of 20 mg once daily when required.

PANTOCID® 20 is indicated for long-term management and prevention of relapse in gastro-esophageal reflux disease (GERD).

PANTOCID® 20 is indicated for the prevention of gastroduodenal lesions and dyspeptic symptoms induced by non-selective non-steroidal anti-inflammatory drugs (NSAID's) in patients at risk, and with a need for continuous NSAID treatment.

4.2 Posology and method of administration

Posology

Duodenal ulcer

The recommended dose is **PANTOCID® 40** once daily. The total treatment with oral **PANTOCID®** should be 2 to 4 weeks. If the duodenal ulcer has been demonstrated to be associated with *Helicobacter pylori* infection, **PANTOCID® 40** used in combination with appropriate antibiotics may be useful.

Gastric ulcer

The recommended dose is **PANTOCID® 40** once daily for 4 to 8 weeks.

In the case of a suspected gastric ulcer, malignancy of the gastric ulcer should be excluded, as treatment could conceal the symptoms and may delay diagnosis.

Reflux oesophagitis

The recommended dose is **PANTOCID® 40** once daily for 4 to 8 weeks.

Zollinger-Ellison Syndrome

For management of Zollinger-Ellison Syndrome patients should start their treatment with a daily dose of 80 mg (2 tablets of **PANTOCID® 40**). Thereafter, the dosage can be titrated up or down as needed using measurements of gastric acid secretion as a guide. With doses above 80 mg daily, the dose should be divided and given twice daily.

Mild gastro-oesophageal reflux disease

The recommended oral dose is 20 mg **PANTOCID®** per day. A 4-week period is usually required for healing of mild gastro-oesophageal reflux disease. If symptom control has not been achieved after four weeks of treatment with the prescribed daily dose, further investigation is recommended. In patients with healed reflux disease, reoccurring symptoms can be controlled using an on-demand regimen of 20 mg once daily when required.

Long-term management and prevention of relapse in gastro-oesophageal reflux disease

For long-term management a maintenance dose of one **PANTOCID® 20** tablet per day is recommended, increasing to **PANTOCID® 40** mg per day if a relapse occurs. After healing of the relapse, the dose can be reduced to **PANTOCID® 20**. Experience with long-term administration is limited.

For prevention of gastro-duodenal lesions and dyspeptic symptoms induced by non-selective nonsteroidal anti-inflammatory drugs (NSAID's) in patients at risk and with a need for continuous NSAID treatment, the recommended oral dose is one **PANTOCID® 20** tablet per day.

Special populations

Elderly patients

No dosage adjustment is necessary in the elderly.

Impaired renal function

No dosage adjustment is required in the presence of impaired renal function.

Impaired liver function

A daily dose of 20 mg **PANTOCID®** should not be exceeded in patients with mild to moderately severe liver impairment (see Section 4.4 and 5.2).

Paediatric population

Safety and efficacy in children has not been established (see section 4.3).

Method of administration

Oral use.

The recommended once daily dose of **PANTOCID®** should be taken in the morning.

PANTOCID® should be swallowed whole with a little water either before or during breakfast.

4.3 Contraindications

- Hypersensitivity to pantoprazole, or to any of the ingredients of **PANTOCID®** (see Section 6.1).
- Severely impaired liver function (see Section 4.4).
- Safety and efficacy in children has not been established.
- **PANTOCID®** should not be co-administered with atazanavir (see Section 4.5).

4.4 Special warnings and precautions for use

Liver failure

In patients with severe liver impairment the liver enzymes should be monitored regularly during treatment with **PANTOCID®**, particularly on long-term use. In the case of a rise of the liver enzymes **PANTOCID®** should be discontinued (see Section 4.3).

Mild gastro-intestinal complaints

PANTOCID® is not indicated for mild gastro-intestinal complaints such as nervous dyspepsia.

Clostridium difficile-associated diarrhoea

Published observational studies suggest that proton pump inhibitor therapy, like **PANTOCID®**, may be associated with an increased risk of Clostridium difficile-associated diarrhoea, especially in hospitalised patients. This diagnosis should be considered for diarrhoea that does not improve (see Section 4.8)

Gastrointestinal infections caused by bacteria

Treatment with **PANTOCID®** may lead to a slightly increased risk of gastrointestinal infections caused by bacteria such as *Salmonella* and *Campylobacter* or *C. difficile* especially in hospitalised patients. **PANTOCID®**, like all proton pump inhibitors (PPIs), might be expected to increase the counts of bacteria normally present in the upper gastrointestinal tract. This diagnosis should be considered for diarrhoea that does not improve (see section 4.8).

Co-administration with anticoagulants

The response to anticoagulants such as warfarin may be affected by any concomitant medication. It is therefore good practice to monitor the patient with additional PT (prothrombin time)/INR (international normalised ratio) determinations when **PANTOCID®** is initiated, discontinued or taken irregularly. Changes in absorption should be observed when medicines whose absorption is pH-dependent, e.g. ketoconazole, are taken concomitantly.

Co-administration with NSAIDs

The use of **PANTOCID®** as a preventive of gastroduodenal ulcers induced by non-selective non-steroidal anti-inflammatory drugs (NSAIDs) should be restricted to patients who require continued NSAID treatment and have an increased risk to develop gastrointestinal complications.

Co-administration with HIV protease inhibitors

Co-administration of **PANTOCID®** is not recommended with HIV protease inhibitors for which absorption is dependent on acidic intragastric pH such as atazanavir, nelfinavir, due to significant reduction in their bioavailability (see section 4.5).

Gastric malignancy

Prior to treatment, or in the presence of any alarm symptom (e.g. significant unintentional weight loss, recurrent vomiting, dysphagia, haematemesis, anaemia or melaena), the possibility of malignancy of gastric ulcer or a malignant disease of the oesophagus should be excluded, as the treatment with **PANTOCID®** may alleviate the symptoms of malignant ulcers and can thus delay diagnosis.

Diagnosis of reflux oesophagitis should be confirmed by endoscopy.

Cyanocobalamin (Vitamin B12) deficiency

Daily treatment with any acid-blocking medicines over a long period of time (e.g. longer than 3 years) may lead to malabsorption of cyanocobalamin caused by hypo- or achlorhydria. Rare cases of cyanocobalamin deficiency under acid-blocking therapy have been reported in the literature. This should be considered when respective clinical symptoms are observed.

Hypomagnesaemia

Severe hypomagnesaemia has been rarely reported in patients treated with proton pump inhibitors (PPIs) like pantoprazole for at least three months, and in most cases for a year. Serious manifestations of hypomagnesaemia such as fatigue, tetany, delirium, convulsions, dizziness and ventricular arrhythmia can occur but they may begin insidiously and be overlooked. Hypomagnesaemia may lead to hypoalcaemia and/or hypokalaemia (see section 4.8). In most affected patients, hypomagnesaemia (and hypomagnesaemia associated hypocalcaemia and/or hypokalaemia) improved after magnesium replacement and discontinuation of the PPI.

For patients expected to be on prolonged treatment or who take PPIs with digoxin or medicinal products that may cause hypomagnesaemia (e.g., diuretics), health care professionals should consider measuring magnesium levels before starting PPI treatment and periodically during treatment.

Subacute cutaneous lupus erythematosus (SCLE)

Proton pump inhibitors are associated with very infrequent cases of SCLE. If lesions occur, especially in sun-exposed areas of the skin, and if accompanied by arthralgia, the patient should seek medical help promptly and the health care professional should consider stopping Pantoprazole. SCLE after previous treatment with a proton pump inhibitor may increase the risk of SCLE with other proton pump inhibitors.

Renal failure

Interstitial nephritis may progress to chronic renal inflammation and renal failure as it is not necessarily reversed when treatment is discontinued. The daily dose of **PANTOCID®** should not be exceeded in elderly patients or those with impaired renal function.

Acute Interstitial Nephritis:

Acute interstitial nephritis has been observed in patients taking proton pump inhibitors (PPIs) including **PANTOCID®**. Acute interstitial nephritis may occur at any point during PPI therapy and is generally attributed to an idiopathic hypersensitivity reaction and is associated with damage to the tubulointerstitium, leading to acute kidney injury. Patients may present with varying signs and symptoms from symptomatic hypersensitivity reactions to non-specific symptoms of decreased renal function (e.g., malaise, nausea, anorexia). In reported case series, some patients were diagnosed on biopsy and in the absence of extra-renal manifestations (e.g. fever, rash or arthralgia). Interstitial nephritis may lead to renal failure. Discontinue **PANTOCID®** if acute interstitial nephritis develops (see section 4.8).

Long term treatment

In long-term treatment, especially when exceeding a treatment period of 1 year, patients should be kept under regular surveillance.

Interference with laboratory tests

Increased Chromogranin A (CgA) level may interfere with investigations for neuroendocrine tumours. To avoid this interference, Pantoprazole treatment should be stopped for at least 5 days before CgA measurements (see section 5.1). If CgA and gastrin levels have not returned to reference range after initial measurement. Measurements should be repeated 14 days after cessation of proton pump inhibitor treatment.

Bone fractures

Proton pump inhibitors, especially if used in high doses and over long durations (>1 year), may modestly increase the risk of hip, wrist and spine fracture, predominantly in the elderly or in presence of other recognised risk factors.

Observational studies suggest that proton pump inhibitors may increase the overall risk of fracture by 10-40%. Some of this increase may be due to other risk factors. Patients at risk of osteoporosis should receive care according to current clinical guidelines and they should have an adequate intake of vitamin D and calcium.

Combination therapy

In the case of combination therapy, the summaries of product characteristics of the respective medicines should be observed.

Lactose

Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose galactose malabsorption should not take this medicine.

4.5 Interaction with other medicines and other forms of interaction

Concomitant intake of food has no influence on the bioavailability.

Medicinal products with pH dependent absorption parmacokinetics

PANTOCID® may reduce or increase the absorption of medicines whose absorption is pH-dependent, e.g. ketoconazole, itraconazole, posaconazole and other medicines like erlotinib.

HIV protease inhibitors

Co-administration of pantoprazole is not recommended with HIV protease inhibitors for which absorption is dependenton acidic intragastric pH such as atazanavir due to significant reduction in their bioavailability (see section 4.4).

Atazanavir: It has been shown that co-administration of atazanavir/ritonavir with omeprazole or atazanavir with lansoprazole resulted in a substantial reduction in the bioavailability of atazanavir. The absorption of atazanavir is pH-dependent. Therefore, pantoprazole must not be co-administered with atazanavir.
If the combination of HIV protease inhibitors with a proton pump inhibitor is judged unavoidable, close clinical monitoring (e.g. virus load) is recommended. A **PANTOCID®** dose of 20 mg per day should not be exceeded. Dosage of the HIV protease inhibitor may need to be adjusted.

Coumarin anticoagulants (phenprocoumon or warfarin)

The response to anticoagulants such as warfarin, phenprocoumon and acenocoumarol may be affected by any concomitant medicine. There have been reports of increased INR and prothrombin time in patients receiving PPIs and warfarin or phenprocoumon concomitantly. Increases in INR and prothrombin time may lead to abnormal bleeding, and even death. It is therefore good practice to monitor the patient with additional PT (prothrombin time) /INR (international normalised ratio) determinations when **PANTOCID®** is initiated, discontinued or taken irregularly.

Inhibitors of CYP2C19

Inhibitors of CYP2C19, such as fluvoxamine, could increase the systemic exposure of pantoprazole. A dose reduction may be considered for patients treated long-term with high doses of **PANTOCID®**, or those with hepatic impairment.

Enzyme inducers affecting CYP2C19 and CYP3A4

Inhibitors of CYP2C19 such as fluvoxamine could increase the systemic exposure of pantoprazole. A dose reduction may be considered for patients treated long-term with high doses of pantoprazole, or those with hepatic impairment.
Enzyme inducers affecting CYP2C19 and CYP3A4, such as rifampicin and St John´s wort (Hypericum perforatum), may reduce the plasma concentrations of PPIs that are metabolized through these enzyme systems.

Methotrexate

Concomitant use of PPIs, including **PANTOCID®**, with methotrexate (primarily at high dose) may elevate and prolong serum levels of methotrexate and/or its metabolite hydroxymethotrexate, possibly leading to methotrexate toxicities.

Other interaction studies

The active ingredient of **PANTOCID®** is metabolised in the liver via the cytochrome P450 enzyme system. The main metabolic pathway is demethylation by CYP2C19 and other metabolic pathways include oxidation by CYP3A4. An interaction of **PANTOCID®** with other medicines or compounds which are metabolised using the same enzyme system cannot be excluded.

No clinically significant interactions were, however, observed in specific tests with a number of such medicines or compounds, namely antipyrine, caffeine, carbamazepine, diazepam, diclofenac, digoxin, ethanol, glibenclamide, metoprolol, naproxen, nifedipine, phenytoin, piroxicam, theophylline, warfarin and oral contraceptives. However, the response to anti-coagulants, such as warfarin, may be affected by any concomitant medication.

There were no interactions reported with concomitantly administered antacids.

No clinically significant interaction studies were reported by concomitantly administering pantoprazole with the respective antibiotics (clarithromycin, metronidazole, amoxicillin) no clinically relevant interactions were found.

4.6 Fertility, pregnancy and lactation

Safety in pregnancy and during lactation has not been established.

Pregnancy

Safety in pregnancy has not been established. Animal studies have shown reproductive toxicity. As a precautionary measure, it is preferable to avoid the use of **PANTOCID®** during pregnancy.

Breastfeeding

Safety during lactation has not been established. There is insufficient information on the excretion of pantoprazole in human milk but excretion into human milk has been reported. A risk to the newborns/infants cannot be excluded. Therefore, breastfeeding while on **PANTOCID®** is not recommended.

Fertility

There was no evidence of impaired fertility reported following the administration of pantoprazole in animal studies

4.7 Effects on ability to drive and use machines

PANTOCID® has no or negligible influence on the ability to drive and use machines.
Adverse medicine reactions such as dizziness and visual disturbances may occur (see section 4.8). If affected patients should not drive or operate machines.

4.8 Undesirable effects

Tabulated list of adverse reactions

Table 1

System Organ Class	Frequent	Less Frequent	Frequency Unknown
Infections and infestations			*Clostridium difficile* Associated diarrhoea*.
Blood and the lymphatic system disorders		Agranulocytosis, Leukopenia, thrombocytopenia, pancytopenia.	

Immune system disorders		Hypersensitivity reactions including anaphylactic reactions and anaphylactic shock.	
Metabolism and nutrition disorders		Increased liver enzymes (transaminases,γ-GT), elevated triglycerides and increased body temperature, weight changes, Hyperlipidaemias and lipid increases (triglycerides, cholesterol)	Hyponatraemia, Hypomagnesaemia (see section 4.4). Hypokalaemia, Hypocalcaemia**
Nervous system disorders	Headache	Dizziness, or disturbances in vision (blurred vision). Taste disorders	Paraesthesia
Psychiatric disorders		Sleep disorders, Mental depression, Depression (and all aggravations), Disorientation (and all aggravations),	Hallucinations* (especially in pre-disposed patients, and all aggravations of these symptoms in pre-existence), confusion*
Eye disorders		Blurred vision / Disturbances in vision	
Gastric-intestinal disorders	Upper abdominal pain, diarrhoea,	Nausea, vomiting, dry mouth, abdominal distension and	Microscopic colitis*

	constipation or flatulence, Fundic gland polyps (benign)	bloating, abdominal pain and discomfort	
Hepato-biliary disorders		Increased bilirubin, Increased liver enzymes (transaminases, γ-GT)	Severe hepatocellular damage* leading to jaundice* with or without hepatic failure*.
Skin and subcutaneous tissue disorders		Allergic reactions such as pruritus, and skin rash, urticaria, angioedema, exanthema, eruption and severe skin reactions such as Stevens-Johnson syndrome*, erythema multiforme*, Lyell syndrome* and photosensitivity*	Drug reaction with eosinophilia and systemic symptoms (DRESS), subacute cutaneous lupus erythematosus*
Musculoskeletal connective tissue and bone disorders		Fracture of the hip, wrist or spine (see section 4.4) Arthralgia, myalgia.	Muscle spasm as a consequence of electrolyte disturbance*, Hyponatraemia, hypomagnesaemia, hypocalcaemia in association with hypomagnesaemia

Renal and urinary disorders		Interstitial nephritis* with possible progression to renal failure	Tubulointerstitial nephritis (TIN) (with possible progression to renal failure)
Reproductive system and breast disorders		Gynaecomastia	
General disorders and administration site conditions		Asthenia , fatigue and malaise, Body temperature increased, Peripheral oedema	

*Post-marketing reports.

**Hypocalcaemia in association with hypomagnesaemia.

Reporting of suspected adverse reactions:

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

Suspected adverse reactions can also be reported directly to the HCR via email:

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

4.9 Overdose

There are no known symptoms of overdosage in man. As pantoprazole is extensively protein bound, it is not readily dialysable. No specific therapeutic recommendation can be made in cases of overdosage. Treatment is symptomatic and supportive.

Systemic exposure with up to 240 mg administered intravenously over 2 minutes was well tolerated.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Proton pump inhibitors.

ATC code: A02B C02

Pharmacological classification: A 11.4.3 Medicines acting ongastric-intestinal tract.

Mechanism of action

Pantoprazole is a proton pump inhibitor, i.e. it inhibits specifically and dose-proportionally H+, K+-ATPase, the enzyme, which is responsible for gastric acid secretion in the parietal cells of the stomach.

Pantoprazole is a substituted benzimidazole, which accumulates in the acidic compartment of the parietal cells after absorption. In the parietal cell it is protonated and chemically re-arranged to the active inhibitor, a cyclic sulphonamide, which binds to the H+, K+-ATPase, thus inhibiting the proton pump and causing suppression of stimulated and basal gastric acid secretion after single and multiple intravenous and oral pantoprazole dosing. Because pantoprazole acts distal to the receptor level, it can influence gastric acid secretion irrespective of the nature of the stimulus.

Pantoprazole exerts its full effect in a strongly acidic environment (pH < 3) and remains mostly inactive at higher pH values, which explains its selectivity for the acid secreting parietal cells of the stomach. Therefore, the complete pharmacological and therapeutic effect for pantoprazole can only be achieved in the acid-secreting parietal cells. By means of a feedback mechanism this effect is diminished at the same rate as acid secretion is inhibited.

Effect on gastric acid secretion

Following oral administration, pantoprazole inhibits the pentagastrin-stimulated gastric acid secretion. The mean acid inhibition was 85 %, 2½ to 3½ hours after dosing with 40 mg/day for 7 days. Pantoprazole maintains the physiological pH-rhythm. The values, however, are shifted to higher levels. During the night, periods of pH values approximating placebo have been found to occur.

Although pantoprazole has a half-life of approximately 1 hour, the antisecretory effect increases during repeated once daily administration, demonstrating that the duration of action markedly exceeds the serum elimination half-life.

5.2 Pharmacokinetic properties

Absorption and distribution

Pantoprazole is unstable in acid and is administered orally in the form of an enteric-coated tablet. Absorption takes place in the small intestine. On average, the maximum serum/plasma concentrations are approximately 2 to 3 µg/ml about 2½ hours after administration of 40 mg pantoprazole daily, as a single or multiple dose in healthy volunteers. The absolute systemic bioavailability of pantoprazole from single and multiple oral doses of pantoprazole is approximately 77 %. Concomitant intake of food had no influence on AUC, maximum serum concentration and thus bioavailability. Only the variability of the lag-time will be increased by concomitant food intake. The plasma kinetics for pantoprazole after oral administration are linear over the dose range 10 – 80 mg.

Pantoprazole's serum protein binding is about 98 %. Volume of distribution is about 0.15 L/kg.

Biotransformation

Pantoprazole is almost exclusively metabolised in the liver. The main metabolite is desmethylpantoprazole, which is conjugated with sulphate Other metabolic pathway includes oxidation by CYP3A4.

Elimination

Renal elimination represents the most important route of excretion (approximately 80 %) for the metabolites of pantoprazole. The balance is excreted with the faeces. The half-life of the main metabolite is approximately 1½ hours, which is slightly longer than that of pantoprazole.

Linearity/non-linearity:

The plasma kinetics for pantoprazole administration are linear over the dose range 10 - 80 mg.

Special populations:

Pharmacokinetic profile in patients with impaired liver or renal function

For patients with mild to moderately severe hepatic cirrhosis the elimination half-life values increase between 7 to 9 hours. The AUC values increase by a factor of 5 to 8, while the maximum serum concentration only increases by a factor of 1,5 in comparison with healthy subjects.

In patients with renal impairment the half-life of the main metabolite is moderately increased, but there is no accumulation at therapeutic doses. The half-life of pantoprazole in patients with renal impairment is comparable to the half-life of pantoprazole in healthy subjects. Pantoprazole is poorly dialysed. A slight increase in AUC and C_{max} occurs in elderly volunteers compared with younger people.

Poor metabolisers

Approximately 3 % of the European population lack a functional CYP2C19 enzyme and are called poor metabolisers. In these individuals the metabolism of pantoprazole is probably mainly catalysed by CYP3A4. After a single-dose administration of 40 mg pantoprazole, the mean area under the plasma concentration-time curve was approximately 6 times higher in poor metabolisers than in subjects having a functional CYP2C19 enzyme (extensive metabolisers). Mean peak plasma concentrations were increased by about 60 %. These findings have no implications for the posology of pantoprazole.

Elderly

A slight increase in AUC and C_{max} occurs in elderly volunteers compared with younger people.

Paediatric population

Following administration of single oral doses of 20 or 40 mg pantoprazole to children aged 5 - 16 years AUC and C_{max} were in the range of corresponding values in adults.

Following administration of single i.v. doses of 0.8 or 1.6 mg/kg pantoprazole to children aged 2 - 16 years there was no significant association between pantoprazole clearance and age or weight. AUC and volume of distribution were in accordance with data from adults.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Active ingredient: 20 mg and 40 mg pantoprazole.

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.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 Months

6.4 Special precautions for storage

Store at or below 25 °C.

Protect from light and moisture.

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

6.5 Nature and contents of container

PANTOCID® 20/40 may be presented in either blister packs or white round HDPE bottles packs.

Not all pack types may be marketed simultaneously.

HDPE bottle pack

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.

6.6 Special precautions for disposal and other handling

No special requirements.

7 HOLDER OF CERTIFICATE OF REGISTRATION

Ranbaxy Pharmaceuticals (Pty) Ltd

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8 REGISTRATION NUMBER(S)

PANTOCID® 20: 41/11.4.3/0787

PANTOCID® 40: A40/11.4.3/0482

9 DATE OF FIRST AUTHORISATION

PANTOCID® 20: 01/10/2010

PANTOCID® 40: 01/12/2006

10 DATE OF REVISON OF THE TEXT

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

18 March 2026