For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only

PANSPED 40

(Pantoprazole Tablets I.P.)

1. Generic Name

Pantoprazole Tablets I.P.

2. Qualitative and quantitative composition

Each enteric coated tablet contains:

Pantoprazole Sodium I.P.

(as sesquihydrate)

Equivalent to Pantoprazole 40 mg

Colour: Titanium Dioxide I.P.

The excipients used are Mannitol, Crospovidone, Sodium Carbonate anhydrous, Hydroxypropylcellulose, Sodium Carbonate anhydrous, Crospovidone, Calcium Stearate, Hydroxypropylmethylcellulose, Titanium Dioxide, Propylene Glycol, Triethyl Citrate, Eudragit, Talc.

3. Dosage form and strength

Dosage form: Enteric coated tablet

Strength: 40 mg

4. Clinical particulars

4.1 Therapeutic indication

Gastric ulcer, Duodenal ulcer, Zollinger-Ellison-syndrome and Gastro-esophageal reflux diseases (GERD)

4.2 Posology and method of administration

Posology

Gastro-esophageal reflux diseases

The recommended dose is 40 mg pantoprazole (one tablet) per day. It might be necessary to take the tablets for 2-3 consecutive days to achieve improvement of symptoms. Once complete relief of symptoms has occurred, treatment should be discontinued. The treatment should not exceed 4 weeks without consulting a doctor. If no symptom relief is obtained within 2 weeks of continuous treatment, the patient should be instructed to consult a doctor.

Gastric ulcer

One tablet of Pantoprazole per day. In individual cases the dose may be doubled (increase to 2 tablets Pantoprazole daily) especially when there has been no response to other treatment. A

4-week period is usually required for the treatment of gastric ulcers. If this is not sufficient, healing will usually be achieved within a further 4 weeks.

Duodenal ulcer

One tablet of Pantoprazole per day. In individual cases the dose may be doubled (increase to 2 tablets Pantoprazole daily) especially when there has been no response to other treatment. A duodenal ulcer generally heals within 2 weeks. If a 2-week period of treatment is not sufficient, healing will be achieved in almost all cases within a further 2 weeks.

Zollinger-Ellison-Syndrome

For the long-term management of Zollinger-Ellison-Syndrome and other pathological hypersecretory conditions patients should start their treatment with a daily dose of 80 mg (2 tablets of Pantoprazole 40 mg). Thereafter, the dose can be titrated up or down as needed using measurements of gastric acid secretion to guide. With doses above 80 mg daily, the dose should be divided and given twice daily. Treatment duration in Zollinger-Ellison syndrome and other pathological hypersecretory conditions is not limited and should be adapted according to clinical needs.

Special populations

Patients with hepatic Impairment

A daily dose of 20 mg pantoprazole (1 tablet of 20 mg pantoprazole) should not be exceeded in patients with severe liver impairment. Pantoprazole must not be used in combination treatment for eradication of H. pylori in patients with moderate to severe hepatic dysfunction since currently no data are available on the efficacy and safety of Pantoprazole in combination treatment of these patients.

Patients with renal Impairment

No dose adjustment is necessary in patients with impaired renal function. Pantoprazole must not be used in combination treatment for eradication of H. pylori in patients with impaired renal function since currently no data are available on the efficacy and safety of Pantoprazole in combination treatment for these patients.

Older people

No dose adjustment is necessary in elderly patients.

Paediatric population

Pantoprazole is not recommended for use in children and adolescents below 18 years of age due to insufficient data on safety and efficacy.

Method of administration

Pantoprazole 40 mg delayed release tablets should not be chewed or crushed, and should be swallowed whole with liquid before a meal.

4.3 Contraindications

Hypersensitivity to the active substance, or to any of the excipients. Co-administration with atazanavir (see section 4.5).

4.4 Special warnings and precautions for use

Hepatic Impairment

In patients with severe liver impairment, the liver enzymes should be monitored regularly during treatment with pantoprazole, particularly on long-term use. In the case of a rise of the liver enzymes, the treatment should be discontinued.

Combination therapy

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

Gastric malignancy

Symptomatic response to pantoprazole may mask the symptoms of gastric malignancy and may delay diagnosis.In the presence of any alarm symptom (e. g. significant unintentional weight loss, recurrent vomiting, dysphagia, haematemesis, anaemia or melaena) and when gastric ulcer is suspected or present, malignancy should be excluded. Further investigation is to be considered if symptoms persist despite adequate treatment.

Co-administration with HIV protease inhibitors

Co-administration of pantoprazole is not recommended with HIV protease inhibitors for which absorption is dependent on acidic intragastric pH such as atazanavir, due to significant reduction in their bioavailability.

Influence on vitamin B12 absorption

In patients with Zollinger-Ellison syndrome and other pathological hypersecretory conditions requiring long-term treatment, pantoprazole, as all acid-blocking medicines, may reduce the absorption of vitamin B12 (cyanocobalamin) due to hypo- or achlorhydria. This should be considered in patients with reduced body stores or risk factors for reduced vitamin B12 absorption on long-term therapy or if respective clinical symptoms are observed.

Long term treatment

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

Gastrointestinal infections caused by bacteria

Treatment with Pantoprazole may lead to a slightly increased risk of gastrointestinal infections caused by bacteria such as Salmonella and Campylobacter and C. difficile.

Hypomagnesaemia

Severe hypomagnesaemia has been reported in patients treated with 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. In most affected patients, hypomagnesaemia 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.

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 older people 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.

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.

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.

4.5 Drugs interactions

Pantoprazole may reduce the absorption of active substances whose bioavailability is dependent on the gastric pH (e.g. ketoconazole).

It has been shown that co-administration of atazanavir 300 mg/ritonavir 100 mg with omeprazole (40 mg once daily) or atazanavir 400 mg with lansoprazole (60 mg single dose) to healthy volunteers 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 (see section 4.3).

Although no interaction during concomitant administration of phenprocoumon or warfarin has been observed in clinical pharmacokinetic studies, a few isolated cases of changes in International Normalised Ratio (INR) have been reported during concomitant treatment in the post-marketing period. Therefore, in patients treated with coumarin anticoagulants (e.g. phenprocoumon or warfarin), monitoring of prothrombin time/INR is recommended after initiation, termination or during irregular use of pantoprazole.

Concomitant use of high dose methotrexate (e.g. 300 mg) and proton-pump inhibitors has been reported to increase methotrexate levels in some patients. Therefore in settings where high-dose methotrexate is used, for example cancer and psoriasis, a temporary withdrawal of pantoprazole may need to be considered.

Pantoprazole is metabolized in the liver via the cytochrome P450 enzyme system. Interaction studies with carbamazepine, caffeine, diazepam, diclofenac, digoxin, ethanol, glibenclamide,

metoprolol, naproxen, nifedipine, phenytoin, piroxicam, theophylline and an oral contraceptive containing levonorgestrel and ethinyl oestradiol did not reveal clinically significant interactions. However, an interaction of pantoprazole with other substances which are metabolised by the same enzyme system cannot be excluded.

There were no interactions with concomitantly administered antacids.

4.6 Fertility, pregnancy and lactation

Pregnancy

There are no adequate data from the use of pantoprazole in pregnant women. Studies in animals have shown reproductive toxicity. Preclinical studies revealed no evidence of impaired fertility or teratogenic effects (see section 5.3). The potential risk for humans is unknown. Pantoprazole should not be used during pregnancy.

Breast-feeding

It is unknown whether pantoprazole is excreted in human breast milk. Animal studies have shown excretion of pantoprazole in breast milk. Pantoprazole should not be used during breast-feeding.

Fertility

There was no evidence of impaired fertility following the administration of pantoprazole in animal studies (see section 5.3).

4.7 Effects on ability to drive and use machines

Pantoprazole has no or negligible influence on the ability to drive and use machines. However, adverse reactions such as dizziness and visual disturbances may occur (see section 4.8). If affected, patients should not drive or use machines.

4.8 Undesirable effects

Summary of the safety profile

Approximately 5% of patients can be expected to experience adverse reactions. The most commonly reported adverse reactions are diarrhoea and headache, both occuring in approximately 1% of patients.

Tabulated list of adverse reactions

The following adverse reactions have been reported with pantoprazole.

Within the following table, adverse reactions are ranked under the MedDRA frequency classification: Very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000), not known (cannot be estimated from the available data).

Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness.

Adverse reactions with pantoprazole in clinical trials and post-marketing experience

Frequency	Uncommon	Rare	Very rare	Not known

System Organ Class				
Blood and lymphatic system disorders		Agranulocytosis	Thrombocytopenia; Leukopenia, Pancytopenia	
Immune system disorders		Hypersensitivity (incl. anaphylactic reactions and anaphylactic shock)		
Metabolism and nutrition disorders		Hyperlipidaemias and lipid increases (triglycerides, cholesterol); Weight changes		Hyponatraemia, Hypomagnesaemia
Psychiatric disorders	Sleep disorders	Depression (and all aggravations)	Disorientation (and all aggravations)	Hallucination; Confusion (especially in pre-disposed patients, as well as the aggravation of these symptoms in case of pre-existence)
Nervous system disorders	Headache; Dizziness	Taste disorders		
Eye disorders		Disturbances in vision / blurred vision		
Gastrointestinal disorders	Diarrhoea; Nausea / vomiting; Abdominal distension and bloating; Constipation; Dry mouth; Abdominal pain and discomfort			
Hepatobiliary disorders	Liver enzymes increased (transaminases, γ-GT)	Bilirubin increased		Hepatocellular injury; Jaundice; Hepatocellular failure
Skin and subcutaneous tissue disorders	Rash / exanthema /	Urticaria; Angioedema		Stevens-Johnson syndrome; Lyell syndrome; Erythema

	eruption; Pruritus			multiforme; Photosensitivity Subacute cutaneous lupus erythematosus (see section 4.4).
Musculoskeletal and connective tissue disorders		Arthralgia; Myalgia		
Renal and urinary disorders				Interstitial nephritis; Acute Kidney Injury
Reproductive system and breast disorders		Gynaecomastia		
General disorders and administration site conditions	Asthenia, fatigue and malaise	Body temperature increased; Oedema peripheral		

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via any point of contact of Torrent Pharma available at: http://www.torrentpharma.com/Index.php/site/info/adverse_event_reporting.

4.9 Overdose

There are no known symptoms of overdose in man.

Doses up to 240 mg administered intravenously over 2 minutes were well tolerated. As pantoprazole is extensively protein bound, it is not readily dialysable.

In the case of overdose with clinical signs of intoxication, apart from symptomatic and supportive treatment, no specific therapeutic recommendations can be made.

5. Pharmacological properties

5.1 Mechanism of Action

Pantoprazole is a substituted benzimidazole which inhibits the secretion of hydrochloric acid in the stomach by specific blockade of the proton pumps of the parietal cells.

Pantoprazole is converted to its active form, a cyclic sulphenamide, in the acidic environment in the parietal cells where it inhibits the H+, K+-ATPase enzyme, i. e. the final stage in the production of hydrochloric acid in the stomach.

5.2 Pharmacodynamic properties

Pharmacotherapeutic group: Drugs for acid related disorders, Proton pump inhibitors, ATC code: A02BC02

The inhibition of hydrochloric acid in the stomach is dose-dependent and affects both basal and stimulated acid secretion. In most patients, freedom from heartburn and acid reflux

symptoms is achieved in 1 week. Pantoprazole reduces acidity in the stomach and thereby increases gastrin in proportion to the reduction in acidity. The increase in gastrin is reversible. Since pantoprazole binds to the enzyme distal to the receptor level, it can inhibit hydrochloric acid secretion independently of stimulation by other substances (acetylcholine, histamine, gastrin). The effect is the same whether the active substance is given orally or intravenously.

The fasting gastrin values increase under pantoprazole. On short-term use, in most cases they do not exceed the upper limit of normal. During long-term treatment, gastrin levels double in most cases. An excessive increase, however, occurs only in isolated cases. As a result, a mild to moderate increase in the number of specific endocrine (ECL) cells in the stomach is observed in a minority of cases during long-term treatment (simple to adenomatoid hyperplasia). However, according to the studies conducted so far, the formation of carcinoid precursors (atypical hyperplasia) or gastric carcinoids as were found in animal experiments (see section 5.3) have not been observed in humans.

During treatment with antisecretory medicinal products, serum gastrin increases in response to the decreased acid secretion. Also CgA increases due to decreased gastric acidity. The increased CgA level may interfere with investigations for neuroendocrine tumours.

Available published evidence suggests that proton pump inhibitors should be discontinued between 5 days and 2 weeks prior to CgA measurements. This is to allow CgA levels that might be spuriously elevated following PPI treatment to return to reference range.

5.3 Pharmacokinetic properties

Pharmacokinetics do not vary after single or repeated administration. In the dose range of 10 to 80 mg, the plasma kinetics of pantoprazole are linear after both oral and intravenous administration.

Absorption

Pantoprazole is completely and rapidly absorbed after oral administration. The absolute bioavailability from the tablet was found to be about 77 %. On average, at about 2.0 h - 2.5 h post administration (tmax) of a single 20 mg oral dose, the maximum serum concentrations (Cmax) of about 1-1.5 µg/ml are achieved, and these values remain constant after multiple administration. Concomitant intake of food had no influence on bioavailability (AUC or Cmax), but increased the variability of the lag-time (tlag).

Distribution

Volume of distribution is about 0.15 l/kg and serum protein binding is about 98%.

Biotransformation

Pantoprazole is almost exclusively metabolized in the liver.

Elimination

Clearance is about 0.1 l/h/kg, and terminal half-life (t1/2) about 1 h. There were a few cases of subjects with delayed elimination. Due to the specific binding of pantoprazole to the proton pumps within the parietal cell, the elimination half-life does not correlate with the much longer duration of action (inhibition of acid secretion).

Renal elimination represents the major route of excretion (about 80%) for the metabolites of pantoprazole; the rest is excreted with the faeces. The main metabolite in both serum and urine is desmethylpantoprazole, which is conjugated with sulphate. The half-life of the main metabolite (about 1.5 h) is not much longer than that of pantoprazole.

Special populations

Renal impairment

No dose reduction is recommended when pantoprazole is administered to patients with impaired renal function (including patients on dialysis, which removes only negligible amounts of pantoprazole). As with healthy subjects, the half-life of pantoprazole is short. Although the main metabolite has a longer half-life (2-3h), excretion is still rapid and thus accumulation does not occur.

Hepatic impairment

After administration of pantoprazole to patients with liver impairment (Child-Pugh classes A, B and C) the half-life values increased to between 3 and 7 h and the AUC values increased by a factor of 3-6, whereas the Cmax only increased slightly by a factor of 1.3 compared with healthy subjects.

Elderly

The slight increase in AUC and Cmax in elderly volunteers compared with younger subjects was not clinically relevant.

6. Nonclinical properties

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity and genotoxicity.

In the 2-year carcinogenicity studies in rats, neuroendocrine neoplasms were found. In addition, squamous cell papillomas were found in the forestomach of rats in one study. The mechanism leading to the formation of gastric carcinoids by substituted benzimidazoles has been carefully investigated and allows the conclusion that it is a secondary reaction to the massively elevated serum gastrin levels occurring in the rat during chronic high-dose treatment.

In the 2-year rodent studies an increased number of liver tumors was observed in rats (in one rat study only) and in female mice and was interpreted as being due to pantoprazole's high metabolic rate in the liver.

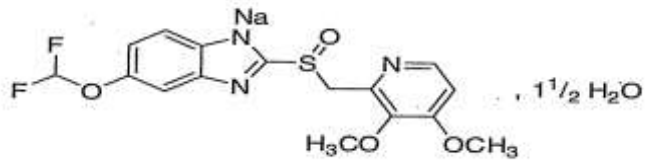
A slight increase of neoplastic changes of the thyroid was observed in the group of rats receiving the highest dose (200 mg/kg) in one 2-year study. The occurrence of these neoplasms is associated with the pantoprazole-induced changes in the breakdown of thyroxine in the rat liver. As the therapeutic dose in man is low, no side effects on the thyroid glands are expected.

In animal studies (rats) 5 mg/kg was the observed NOAEL (No Observed Adverse Effect Level) for embryotoxicity. Investigations revealed no evidence of impaired fertility or teratogenic effects.

Penetration of the placenta was investigated in the rat and was found to increase with advanced gestation. As a result, concentration of pantoprazole in the foetus is increased shortly before birth.

7. Description

Pantoprazole Sodium is sodium 5-(difluromethoxy)_2[[(3,4-dimethoxy-pyridin-2-yl)methyl]sulphinyl]-benzimidazol-1-ide,sesquihydrate. . having molecular formula of C16H14F2N3NaO4S, 1.5 H2O molecular weight is 432.4 the chemical structure is:



Pantoprazole is a white to off white powder.
Product Description: PANSPED 40 white to pale yellow colored, oval shape, biconvex, enteric coated tablets, plain on both sides.

8. Pharmaceutical particulars

8.1 Incompatibilities

None stated

8.2 Shelf-life

Do not use later than the date of expiry.

8.3 Packaging information

PANSPED 40 is packed in blister strips of 10 tablets.

8.4 Storage and handing instructions

Store at a temperature not exceeding 30º C, protected from light and moisture. Keep out of reach of children.

9. Patient counselling information

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

• Keep this leaflet. You may need to read it again.

• If you have any further questions, ask your doctor or pharmacist.

• **This medicine has been prescribed for you only.** Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

• If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet?

9.1.What PANSPED 40 is and what it is used for

9.2.What you need to know before you take PANSPED 40

9.3.How to take PANSPED 40

9.4.Possible side effects

9.5.How to store PANSPED 40

9.6.Contents of the pack and other information

9.1 What PANSPED 40 is and what it is used for

PANSPED 40 contains the active substance pantoprazole, which blocks the 'pump' that produces stomach acid. Hence it reduces the amount of acid in your stomach.

PANSPED 40 is used to treat Adults for Gastro-esophageal reflux diseases (GERD), Gastric and duodenal ulcers, Zollinger-Ellison-Syndrome and other conditions producing too much acid in the stomach.

Reflux is the backflow of acid from the stomach into the gullet ("foodpipe"), which may become inflamed and painful. This may cause you symptoms such as a painful burning sensation in the chest rising up to the throat (heartburn) and a sour taste in the mouth (acid regurgitation). You may experience relief from your acid reflux and heartburn symptoms after just one day of treatment with PANSPED 40, but this medicine is not meant to bring immediate relief. It may be necessary to take the tablets for 2–3 consecutive days to relieve the symptoms. You must talk to a doctor if you do not feel better or if you feel worse after 2 weeks.

9.2 What you need to know before you take PANSPED 40

Do not take PANSPED 40:

– if you are allergic to pantoprazole, or to any of the other ingredients of this medicine.

– if you are taking HIV protease inhibitors such as atazanavir, nelfinavir (for the treatment of HIV-infection). See 'Other medicines and PANSPED 40'.

Warnings and precautions

Talk to your doctor before taking PANSPED 40:

– if you have been treated for heartburn or indigestion continuously for 4 or more weeks – if you are over 55 years old and taking non-prescription indigestion treatment on a daily basis

– if you are over 55 years old with any new or recently changed reflux symptoms

– if you have previously had a gastric ulcer or stomach surgery

– if you have liver problems or jaundice (yellowing of skin or eyes)

– if you regularly see your doctor for serious complaints or conditions

– if you are due to have an endoscopy or a breath test called a C-urea test.

– if you have ever had a skin reaction after treatment with a medicine similar to PANSPED 40 that reduces stomach acid.

– if you are due to have a specific blood test (Chromogranin A) – if you are taking HIV protease inhibitors such as atazanivir, nelfinavir (for the treatment of HIV-infection) at the same time as pantoprazole, ask your doctor for specific advice.

Do not take this product for longer than 4 weeks without consulting your doctor. If your reflux symptoms (heartburn or acid regurgitation) persist for longer than 2 weeks, consult your doctor who will decide about the need for long-term intake of this medicinal product.

If you take PANSPED 40 for longer periods, this may cause additional risks, such as: – reduced absorption of Vitamin B12, and Vitamin B12 deficiency if you already have low body stores of Vitamin B12.

– fracture of your hip, wrist or spine, especially if you already suffer from osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis).

– falling magnesium levels in your blood (potential symptoms: fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness, increased heart rate). Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood. You should talk to your doctor if you have been using this product for more than 4 weeks. Your doctor may decide to perform regular blood tests to monitor your levels of magnesium.

Tell your doctor immediately, before or after taking this medicine, if you notice any of the following symptoms, which could be a sign of another, more serious, disease:

– an unintentional loss of weight (not related to a diet or an exercise programme)

– vomiting, particularly if repeated

– vomiting blood; this may appear as dark coffee grounds in your vomit

– you notice blood in your stools; which may be black or tarry in appearance

– difficulty in swallowing or pain when swallowing – you look pale and feel weak (anaemia)

– chest pain

– stomach pain

– severe and/or persistent diarrhoea, because this medicine has been associated with a small increase in infectious diarrhoea.

– 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 PANSPED 40. Remember to also mention any other ill-effects like pain in your joints.

Your doctor may decide that you need some tests.

If you are due to have a blood test, tell your doctor that you are taking this medicine.

You should not take it as a preventive measure.

If you have been suffering from repetitive heartburn or indigestion symptoms for some time, remember to see your doctor regularly.

Children and adolescents

PANSPED 40 should not be used by children and adolescents under 18 years of age due to a lack of safety information in this younger age group.

Other medicines and PANSPED 40

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

PANSPED 40 may stop certain other medicines from working properly. Especially medicines containing one of the following active substances:

– HIV protease inhibitors such as atazanavir, nelfinavir (for the treatment of HIV-infection). You must not use PANSPED 40 if you are taking HIV protease inhibitors. See 'Do not take PANSPED 40'.

– ketoconazole (used for fungal infections).

– warfarin and phenprocoumon (used to thin blood and prevent clots). You may need further blood tests.

– methotrexate (used to treat rheumatoid arthritis, psoriasis, and cancer)

– if you are taking methotrexate your doctor may temporarily stop your PANSPED 40 treatment because pantoprazole can increase levels of methotrexate in the blood.

Do not take PANSPED 40 with other medicines which limit the amount of acid produced in your stomach, such as another proton pump inhibitor (omeprazole, lansoprazole or rabeprazole) or an H2 antagonist (e.g. ranitidine, famotidine). However, you may take PANSPED 40 with antacids (e.g. magaldrate, alginic acid, sodium bicarbonate, aluminium hydroxide, magnesium carbonate, or combinations thereof), if needed.

Pregnancy and breast-feeding

You should not take this medicine if you are pregnant or while breast-feeding. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

If you experience side effects like dizziness or disturbed vision, you should not drive or use machines.

9.3 How to take PANSPED 40

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is one tablet a day. Method of administration: Take the tablets 1 hour before a meal without chewing or breaking them and swallow them whole with some water.

For the treatment of Gastro-esophageal reflux diseases (GERD). The usual dose is one tablet a day. You should take this medicine for at least 2–3 consecutive days. Stop taking PANSPED 40 when you are completely symptom-free. If you have no symptom-relief after taking this medicine for 2 weeks continuously, consult your doctor. Do not take PANSPED 40 tablets for more than 4 weeks without consulting your doctor.

For the treatment of stomach and duodenal ulcers. The usual dose is one tablet a day. After consultation with your doctor, the dose may be doubled. Your doctor will tell you how long to

take your medicine. The treatment period for stomach ulcers is usually between 4 and 8 weeks. The treatment period for duodenal ulcers is usually between 2 and 4 weeks.

For the long-term treatment of Zollinger-Ellison-Syndrome and of other conditions in which too much stomach acid is produced. The recommended starting dose is usually two tablets a day.

If you take more PANSPED 40 than you should

Tell your doctor or pharmacist if you have taken more than the recommended dose. If possible take your medicine and this leaflet with you.

If you forget to take PANSPED 40

Do not take a double dose to make up for the forgotten dose. Take your next, normal dose, the next day, at your usual time.

If you have any further questions on the use of this medicine ask your doctor or pharmacist.

9.4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor immediately or contact the casualty department at your nearest hospital, if you get any of the following serious side effects. Stop taking this medicine straight away, but take this leaflet and/or the tablets with you.

– Serious allergic reactions (rare: may affect up to 1 in 1,000 people): Hypersensitivity reactions, so-called anaphylactic reactions, anaphylactic shock and angioedema. Typical symptoms are: swelling of the face, lips, mouth, tongue and/or throat, which may cause difficulty in swallowing or breathing, hives (nettle rash), severe dizziness with very fast heartbeat and heavy sweating.

– Serious skin reactions (frequency not known: frequency cannot be estimated from the available data): rash with swelling, blistering or peeling of the skin, losing skin and bleeding around eyes, nose, mouth or genitals and rapid deterioration of your general health, or rash when exposed to the sun.

– Other serious reactions (frequency not known): yellowing of the skin and eyes (due to severe liver damage), or kidney problems such as painful urination and lower back pain with fever.

Other side effects include:

– Common (may affect up to 1 in 10 people): Benign polyps in the stomach

– Uncommon side effects (may affect up to 1 in 100 people): headache; dizziness; diarrhoea; feeling sick; vomiting; bloating and flatulence (wind); constipation; dry mouth; bellyache and discomfort; skin rash or hives; itching; feeling weak, exhausted or generally unwell; sleep disorders; increase in liver enzymes in a blood test; fracture in the hip, wrist or spine.

– Rare side effects: distortion or complete lack of the sense of taste; disturbances in vision such as blurred vision; pain in the joints; muscle pains; weight changes; raised body temperature; swelling of the extremities; depression; increased bilirubin and fat levels in blood (seen in blood test); breast enlargement in males; high fever and a sharp drop in circulating granular white blood cells (seen in blood test).

– Very rare side effects (may affect up to 1 in 10,000 people): disorientation; reduction in the number of blood platelets, which may cause you to bleed or bruise more than normal; reduction in the number of white blood cells, which may lead to more frequent infections; coexisting abnormal reduction in the number of red and white blood cells, as well as platelets (seen in blood tests).

– Frequency not known: hallucination; confusion (especially in patients with a history of these symptoms); decreased level of sodium in blood, decreased level of magnesium in blood, rash, possibly with pain in the joints.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via any point of contact of Torrent Pharma available at: http://www.torrentpharma.com/Index.php/site/info/adverse_event_reporting. By reporting side effects, you can help provide more information on the safety of this medicine.

9.5 How to store PANSPED 40

Store at a temperature not exceeding 30º C, protected from light and moisture.

9.6 Contents of the pack and other information

What PANSPED 40 contains

The active substances in PANSPED 40 is Pantoprazole sodium.

The excipients used are Mannitol, Crospovidone, Sodium Carbonate anhydrous, Hydroxypropylcellulose, Sodium Carbonate anhydrous, Crospovidone, Calcium Stearate, Hydroxypropylmethylcellulose, Titanium Dioxide, Propylene Glycol, Triethyl Citrate, Eudragit, and Talc.

10. Details of manufacturer

Torrent Pharmaceuticals Ltd

32 No. Middle Camp, NH-10,

East Districk, Gangtok, Sikkim-737 135

11. Details of permission or licence number with date

M/563/2010 issued on 23.12.2016

12. Date of revision

JUN/2020

MARKETED BY

TORRENT PHARMACEUTICALS LTD.

Torrent House, Off Ashram Road,

Ahmedabad-380 009, INDIA

IN/PANSPED 40/JUN 20/04/PI