Front Side

355 mm

435 mm

SCHEDULING STATUS: S4

1. NAME OF THE MEDICINE

PRAZTEK 20 mg gastro-resistant tablets
PRAZTEK 40 mg gastro-resistant tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Gastro-resistant tablet contains 22,6 mg of Pantoprazole sodium sesquihydrate equivalent to 20,0mg of Pantoprazole base.
Contains sugar - mannitol 39,364 mg
Each Gastro-resistant tablet contains 45,1 mg of Pantoprazole sodium sesquihydrate equivalent to 40,0mg of Pantoprazole base.
Contains sugar - mannitol 78,728 mg
This medicine contains less than 1 mmol sodium per tablet, that is to say it is essentially "sodium-free".
For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Gastro-resistant tablets.

PRAZTEK 20 mg: Yellow, oval, biconvex, enteric-coated tablets plain on both sides.
PRAZTEK 40 mg: Yellow, oval, biconvex, enteric-coated tablets plain on both sides.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

PRAZTEK 20 mg is indicated for the symptomatic improvement (e.g., heartburn, acid regurgitation, pain on swallowing) and healing of mild gastro-oesophageal reflux disease. In patients with healed reflux disease, recurring symptoms can be controlled using an on-demand regimen of 20 mg once daily when required.

PRAZTEK 20 mg is indicated for long-term management and prevention of relapse in gastro-oesophageal reflux disease.

PRAZTEK 20 mg 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.

PRAZTEK 40 mg is used 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, PRAZTEK 40 mg should be used in combination with appropriate antibiotics.

PRAZTEK 40 mg is indicated in adults for the treatment of Zollinger-Ellison syndrome.

4.2 Posology and method of administration

Posology

Mild gastro-oesophageal reflux disease
The recommended oral dose is PRAZTEK 20 mg per day. A 4-week period is usually required for healing of mild gastro-oesophageal reflux disease. If this is not sufficient, healing will usually be achieved within a further 4 weeks. In patients with healed reflux disease, reoccurring symptoms can be controlled using an on-demand regimen of PRAZTEK 20 mg once daily when required.

Long-term management and prevention of relapse in gastro-oesophageal reflux disease
For long-term management & maintenance dose of one PRAZTEK 20 mg tablet per day is recommended, increasing to 40 mg PRAZTEK per day if a relapse occurs. After healing of the relapse, the dose can be reduced to PRAZTEK 20 mg. Experience with long-term administration is limited.
For prevention of gastro-duodenal 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, the recommended oral dose is one PRAZTEK 20 mg per day.

Duodenal ulcer:
The recommended dose is PRAZTEK 40 mg once daily. The total treatment should be 2 to 4 weeks. If the duodenal ulcer has been demonstrated to be associated with *Helicobacter pylori* infection, PRAZTEK should be used in combination with appropriate antibiotics.

Gastric ulcer:
The recommended dose is PRAZTEK 40 mg, one tablet, once daily for daily 4 to 8 weeks.
In case of suspected gastric ulcer, malignancy of the gastric ulcer should be excluded as treatment could conceal the symptoms and may delay diagnosis.

Refluxes ophagitis:
The recommended dose is PRAZTEK 40 mg, one tablet, once daily for 4 to 8 weeks.
If gastro-oesophageal reflux disease (GORD) symptom control has not been achieved after four weeks of treatment with the prescribed daily dose, especially where differentiation of diagnosis of GORD with weight and oesophageal heartburn is present, further investigation is recommended.

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

Special Populations

Elderly patients:
No dosage adjustment is necessary in the elderly.

Impaired renal and liver function
No dosage adjustment is necessary in the presence of impaired renal function. A daily dose of PRAZTEK 20 mg should not be exceeded in patients with mild to moderately severe liver impairment (see section 4.4 and 5.2).

Paediatric population
PRAZTEK is not recommended for use in children due to limited data on safety and efficacy.

Method of administration

PRAZTEK tablets should be taken in the morning, swallowed whole with a little water either before or during breakfast.
The gastro-resistant tablet should not be crushed because coating prevents pH sensitive degradation in the gut.

4.3 Contraindications

- Hypersensitivity to pantoprazole or to any of the excipients listed in section 6.1.
- Safety and efficacy in children have not been established.
- Severely impaired liver function (see section 4.4).
- PRAZTEK should not be co-administered with HIV protease inhibitors, such as atazanavir or nelfinavir saquinavir (See Section 4.5).

4.4 Special warnings and precautions for use

In the case of combination therapy for the eradication of *H pylori*, the professional information for the antibiotics used in the combination should be observed.

In the presence of any alarm symptoms (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 as treatment with pantoprazole may alleviate symptoms and delay diagnosis. Further investigation is to be considered if symptoms persist despite adequate treatment.

Hepatic impairment
In patients with severe liver impairment the liver enzymes should be monitored regularly during treatment with PRAZTEK, particularly on long term use. In case of a rise of the liver enzymes PRAZTEK should be discontinued (see section 4.2).

***Clostridium difficile* associated diarrhoea (CDAD)**
PPI therapy such as PRAZTEK may be associated with an increased risk of CDAD.
Pantoprazole, like all proton pump inhibitors, might be expected to increase the counts of bacteria normally present in the upper gastrointestinal tract. Treatment with pantoprazole may lead to a slightly increased risk of gastrointestinal infections caused by bacteria such as *Salmonella*, *Campylobacter* and *Clostridium difficile*.

Influence on vitamin B12 absorption
Daily treatment with any acid-blocking medicines such as PRAZTEK over a long period of time may lead to malabsorption of cyanocobalamin (vitamin B12) caused by hypo-/achlorhydria. Cases of cyanocobalamin deficiency under acid-blocking therapy have been reported. This should be considered when respective clinical symptoms are observed.

Co-administration with non-steroidal anti-inflammatory drugs
Use of pantoprazole for prevention of gastric duodenal lesions and dyspeptic symptoms associated with non-selective non-steroidal anti-inflammatory drugs (NSAIDs) should be restricted to patients who require continued non-selective NSAID treatment and have an increased risk to develop gastrointestinal complications. The increased risk should be assessed according to individual risk factors, e.g., high age (>65 years), history of gastric or duodenal ulcer or upper gastrointestinal bleeding.

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 healthcare professional should consider stopping pantoprazole.

Bone fracture
PPI such as PRAZTEK may be associated with an increased risk for osteoporosis-related fractures of the hip, wrist or spine. The risk of fracture was increased in patients who received high doses, defined as multiple daily doses, and long-term PPI therapy (a year or longer).

Acute interstitial Nephritis (AIN)
Acute interstitial nephritis has been observed in patients taking PPIs including pantoprazole. Acute interstitial nephritis may occur at any point during PPI therapy and is generally associated to an idiopathic hypersensitivity reaction which may progress to kidney injury and/or chronic renal failure. Discontinue PRAZTEK if acute interstitial nephritis develops. Symptoms of AIN may persist even when treatment is discontinued.

Hypomagnesaemia
Hypomagnesaemia has been rarely reported in patients treated with PPIs for at least three months (in most cases after a year of therapy). Serious consequences of hypomagnesaemia include tetany, dysrhythmia, and seizure.
Measuring magnesium levels before starting treatment and periodically during treatment is recommended in patients who are expected to require treatment long term (3 months or longer) and particularly in patients who are taking digoxin or other medicines that may cause hypomagnesaemia (e.g., diuretics).

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, PRAZTEK 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.
Patients should consult their doctor before taking PRAZTEK if they are due to have an endoscopy or urea breath test.

4.5 Interaction with other medicinal products and other forms of interaction

Cytochrome P450 enzyme
Pantoprazole is metabolised in the liver via the cytochrome P450 enzyme system. A study using human liver microsomes suggested that the P450 enzymes CYP2C19 and CYP3A4 are involved in its metabolism. In addition, CYP2D6 and CYP2C9-10 were implicated in another study. An interaction of pantoprazole with other medicines which are metabolised using the same enzyme system cannot be excluded.
However, no clinically significant interactions were observed in specific tests with a number of such medicines, namely carbamazepine, caffeine, diazepam, diclofenac, digoxin, ethanol, glibenclamide, metoprolol, naproxen, nifedipine, phenytoin, piroxicam, theophylline, and the low dose oral contraceptive (levonorgestrel and ethinyl estradiol).There was also no interaction with a concomitantly administered antacid (aluminium hydroxide and magnesium hydroxide).
Enzyme inducers affecting CYP2C19 and CYP3A4 such as rifampicin and St John's wort (*Hypericum perforatum*) may reduce the plasma concentration of PPIs such as PRAZTEK that are metabolised through these enzyme systems.

Coumarin anticoagulants (phenprocoumon or warfarin)
Co-administration of pantoprazole with warfarin or phenprocoumon did not affect the pharmacokinetics of warfarin, phenprocoumon or International Normalised Ratio (INR). However, 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. Patients treated with pantoprazole and warfarin or phenprocoumon may need to be monitored for increase in INR and prothrombin time

Medicines with pH-dependent absorption pharmacokinetics
The absorption of medicines whose bioavailability is pH dependent (e.g., ketoconazole, itraconazole, posaconazole, erlotinib), might be altered due to the decrease in gastric acidity.

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 (see section 4.4), 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 pantoprazole dose of 20 mg per day should not be exceeded. Dosage of the HIV protease inhibitor may need to be adjusted.

Mycophenolate mofetil
Co-administration of PPIs including pantoprazole receiving mycophenolate mofetil has been reported to reduce the exposure to the active metabolite, mycophenolic acid. This is possibly due to a decrease in mycophenolate mofetil solubility at an increased gastric pH. The clinical relevance of reduced mycophenolic acid exposure on organ rejection has not been established in transplant patients receiving PPIs and mycophenolate mofetil. Use pantoprazole with caution in transplant patients receiving mycophenolate mofetil.

Methotrexate
Concomitant use with methotrexate (primarily at high dose), may elevate and prolong serum levels of methotrexate and/or its metabolite, possibly leading to methotrexate toxicities.

Medicines that Inhibit or Induce CYP2C19 (tacrolimus, fluvoxamine)
Concomitant administration of pantoprazole and tacrolimus may increase whole blood levels of tacrolimus, especially in transplant patients who are intermediate or poor metabolisers of CYP2C19. Inhibitors of CYP2C19, such as fluvoxamine, would likely increase the systemic exposure of pantoprazole.

4.6 Fertility, pregnancy, and lactation

Safety in pregnancy and during lactation has not been established.

4.7 Effects on ability to drive and use machines

Pantoprazole does not exert its pharmacological action centrally, therefore it is not expected to adversely affect the ability to drive or use machines, however, adverse drug 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

Summary of the safety profile
The most commonly reported adverse drug reactions (ADRs) were diarrhoea and headache.

For all adverse reactions reported from post-marketing experience, it is not possible to apply any Adverse Reaction frequency and therefore they are mentioned with a "not known" frequency.

Tabulated summary of adverse reactions

The table below lists adverse reactions reported with pantoprazole, ranked under the following frequency classification: frequent, less frequent and frequency not known.

Table 1. Adverse reactions with pantoprazole in clinical trials and post-marketing experience

Frequency System Organ Class	Frequent	Less Frequent	Frequency not known
Infections and Infestations			*Clostridium difficile* associated diarrhoea and increased risk of gastrointestinal infections caused by bacteria such as *Salmonella* and *Campylobacter*
Blood and the lymphatic system		Agranulocytosis, Thrombocytopenia, Leukopenia, Pancytopenia	
Immune system disorders		Hypersensitivity (including anaphylactic reactions and anaphylactic shock)	
Metabolism and nutrition	Hyperlipidaemias and lipid increase (triglycerides, cholesterol); Weight changes		Hyponatraemia, Hypomagnesaemia (*see section 4.4*) Hypocalcaemia in association with hypomagnesaemia; Hypokalaemia
Psychiatric disorders	Sleep disorders	Depression (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	Paraesthesia
Eye disorders	Disturbances in vision / blurred vision		
Gastrointestinal disorders	Fundic gland polyps (benign) Diarrhoea, Nausea ; vomiting; Abdominal distension and bloating; Constipation; Dry mouth; Abdominal pain and discomfort		
Hepatobiliary disorders	Liver enzymes increased (transaminases, GT)	Bilirubin increased	Hepatocellular injury; Jaundice; Hepatocellular failure
Skin and subcutaneous tissue disorders	Rash / exanthema / eruption; Pruritus	Urticaria; Angioedema	Stevens-Johnson syndrome; Lyell syndrome; Erythema multiforme; Photosensitivity; Subacute cutaneous lupus erythematosus (see section 4.4)
Musculoskeletal, connective tissue disorders	Fracture of the hip, wrist or spine (*see section 4.4*)	Arthralgia; Myalgia	Muscle spasm as a consequence of electrolyte disturbances
Renal and urinary disorders			Interstitial nephritis (with possible progression to renal failure)
Reproductive system and breast disorders		Gynaecomastia	
General disorders and administration site conditions	Asthenia, fatigue and malaise	Increased body temperature; peripheral oedema	

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications:https://www.sahpra.org.za/Publication/Index/8

4.9 Overdose

There are no known symptoms of overdose in human. In overdose, side effects can be precipitated and/or be of increased severity (see Section 4.5). As pantoprazole is extensively protein bound, it is not readily dialysable. In case of overdosage, treatment should be symptomatic and supportive measures should be utilised.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacological classification: A 11.4.3 Medicines acting on the gastro-intestinal tract

Pharmacotherapeutic group: Proton pump inhibitors, ATC code: A02BC02

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.

Pharmacodynamic effects
Pantoprazole is a substituted benzimidazole which accumulates in the acidic environment of the parietal cells after absorption. It is converted into the active form, a cyclic sulphenamide which binds to the H^+K^+-ATPase, thus inhibiting the proton pump and causing potent and long-lasting suppression of basal and stimulated gastric acid secretion. As pantoprazole acts distal to the receptor level it can influence gastric acid secretion irrespective of the nature of the stimulus (acetylcholine, histamine, gastrin).
Pantoprazole's selectivity is due to the fact that it only exerts its full effect in a strongly acidic environment (pH < 3), remaining mostly inactive at higher pH values. As a result, its complete pharmacological, and thus therapeutic effect, can only be achieved in the acid-secretory 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
Treatment with pantoprazole causes a reduced acidity in the stomach and thereby an increase in gastrin in proportion to the reduction in acidity. The increase in gastrin is reversible. The effect of pantoprazole sodium oral formulations (tablets and granules) and the intravenous formulation on gastric acidity is comparable.

5.2 Pharmacokinetic properties

Absorption
Pantoprazole is well absorbed after oral administration and the maximal plasma concentration appears after one single oral dose. After single and multiple oral doses, the median time to reach maximum serum concentrations was approximately 2,5 h, with a C_{max} of approximately 2 to 3 µg/ml following a 40 mg pantoprazole daily in healthy volunteers. Terminal half-life is approximately 1 h. Pharmacokinetics do not vary after single or repeated administration. The plasma kinetics of pantoprazole are linear (in the dose range of 10 to 80 mg) after both oral and intravenous administration.
The absolute systemic bioavailability of pantoprazole is approximately 77 %. The AUC is approximately 4,0 mg/L. Concomitant intake of food had no influence on the AUC and C_{max} of the pantoprazole 40 mg tablet and thus its bioavailability.

Distribution
The serum protein binding of pantoprazole is approximately 98 %. Volume of distribution is approximately 0,15 L/kg and clearance is approximately 0,1 L/h/kg.

Metabolism
Pantoprazole is extensively metabolised in the liver through the cytochrome P450 (CYP) system. Pantoprazole metabolism is independent of the route of administration (intravenous or oral). The main metabolic pathway is demethylation, by CYP2C19, with subsequent sulfation; other metabolic pathways include oxidation by CYP3A4.The main metabolite is desmethylpantoprazole, which is conjugated with sulphate. There is no evidence that any of the pantoprazole metabolites have significant pharmacological activity. CYP2C19 displays a known genetic polymorphism due to its deficiency in some sub-populations (e.g., 3 % of Caucasians and African Americans and 17-23 % of Asians). Although these sub-populations of slow pantoprazole metabolisers have elimination half-life values of 3,5 to 10,0 hours, they still have minimal accumulation (623 %) with once daily dosing.

Elimination
Pantoprazole is rapidly eliminated from serum and is almost exclusively metabolised in the liver. Renal elimination represents the most important route of excretion (approximately 80 %) for the metabolites of pantoprazole, the rest are excreted with the faeces. The half-life of the main metabolites (approximately 1,5 h) is not much longer than that of pantoprazole.

Special populations
Pharmacokinetic profile in patients with impaired liver
For patients with mild to moderately severe hepatic cirrhosis the elimination half-life values increase to 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.

Pharmacokinetic profile in patients with impaired renal function
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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Mannitol, crospovidone, sodium carbonate anhydrous, calcium stearate, hydroxypropylmethyl cellulose, povidone, propylene glycol, titanium dioxide, iron oxide yellow, methacrylic acid copolymer, triethyl citrate.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 months from date of manufacture.

6.4 Special precautions for storage

Store at or below 25 °C.
Keep the blisters in the carton until required for use.
Store in the original package in order to protect from light and moisture.
KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents of container

Blister pack:
Tablets are packed in cold form laminate, 25 µm OPA/45 µm Aluminium foil/60 µm PVC and plain 25 µm Aluminium foil/6-8 gsm HSL as the lidding material.
Pack size for 20 mg: 28's
Pack size for 40 mg: 14's and 28's
Not all packs and pack size are necessarily marketed.

6.6 Special precautions for disposal

No special requirements

7. HOLDER OF CERTIFICATE OF REGISTRATION

Macleods Pharmaceuticals SA (Pty) Ltd
Office Block 1, Bassonia Estate Office Park (East),
1 Cussonia Drive, Bassonia Rock, Ext. 12,
Alberton, South Africa.

8. REGISTRATION NUMBER(S)

PRAZTEK 20 mg: 51/11.4.3/1124
PRAZTEK 40 mg: 51/11.4.3/1125

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

21 June 2022

10. DATE OF REVISION OF THE TEXT

–

PRAZTEK
20 mg / 40 mg
(gastro-resistant tablet)
PM03895501

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

PRAZTEK 20 mg and 40 mg gastro-resistant tablets
Pantoprazole sodium sesquihydrate
(contains mannitol)

Read all of this leaflet carefully before you start taking PRAZTEK:
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse, or other health care provider.
- PRAZTEK 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 PRAZTEK is and what it is used for
2. What you need to know before you take PRAZTEK
3. How to take PRAZTEK
4. Possible side effects
5. How to store PRAZTEK
6. Contents of the pack and other information

1. What PRAZTEK is and what it is used for

PRAZTEK is a selective "proton pump inhibitor", a medicine which reduces the amount of acid produced in your stomach. It is used for treating acid-related diseases of the stomach and intestine.

PRAZTEK 20 mg is used for treating:
Mild reflux oesophagitis (inflammation of the oesophagus,a tube that runs from the throat to the stomach), and control of recurring symptoms in patients with healed reflux disease using an on-demand regimen.
Long-term treatment and prevention of relapse reflux disease.
Stomach ulcers caused by medicines called NSAIDs (Non-steroidal Anti-Inflammatory Drugs). Pantoprazole can also be used to stop stomach ulcers from forming if you are taking NSAIDs.
PRAZTEK 40 mg is used for treating:
Reflux oesophagitis. An inflammation of your oesophagus (the tube which connects your throat to your stomach) accompanied by the regurgitation of stomach acid.
An infection with a bacterium called *Helicobacter pylori* in patients with duodenal ulcers and stomach ulcers in combination with two antibiotics (Eradication therapy).
Stomach and duodenal ulcers.
Zollinger-Ellison-Syndrome a digestive disorder that results in too much gastric acid.

2. What you need to know before you take PRAZTEK

Do not take PRAZTEK
- If you are hypersensitive (allergic) to pantoprazole or to any of the other ingredients of PRAZTEK (see list under section 6);
- If you have serious liver problems.
- If you are taking medicines for HIV such as atazanavir or nelfinavir (antiretrovirals): These medicines may not work as well against your HIV infection if you take them with PRAZTEK.
- PRAZTEK must not be given to children as it is not known if it is safe and effective for them.

Warnings and precautions
Tell your doctor or healthcare professional before taking PRAZTEK:
Take special care with PRAZTEK

- If you have severe liver problems or if you ever had problems with your liver in the past. He will check your liver enzymes more frequently, especially when you are taking PRAZTEK as a long-term treatment. In the case of a rise in liver enzymes the treatment should be stopped.
- If you have reduced body stores or risk factors for reduced vitamin B12 and receive pantoprazole long-term treatment, as pantoprazole may lead to a reduced absorption of vitamin B12.
- If you are taking HIV protease inhibitors such as atazanavir or nelfinavir (for the treatment of HIV-infection) at the same time as pantoprazole, ask your doctor for specific advice.
- If you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis). Taking a proton pump inhibitor like pantoprazole, especially over a period of more than one year, may slightly increase your risk of fracture in the hip, wrist, or spine.
- If you are on PRAZTEK 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, 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 you have ever had a skin reaction after treatment with a medicine that reduces stomach acid such as PRAZTEK.

Back Side



- If you get a rash on your skin, especially in areas exposed to the sun, you may need to stop your treatment with **PRAZTEK**. Remember to also mention any other **ill-effects** like pain in your joints.
- If you are due to have a specific blood test (Chromogranin A).

Tell your doctor immediately if you notice any of the following symptoms:

- An unintentional loss of weight.
- 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
- you notice blood in your urine, reduction in urine output and fever.
- difficulty in swallowing or pain when swallowing
- chest pain
- stomach pain
- you look pale and feel weak (anaemia)
- severe and/or persistent diarrhoea, as **PRAZTEK** has been associated with a small increase in infectious diarrhoea.

Your doctor may decide that you need some tests in rule out malignant disease because pantoprazole also alleviates the symptoms of cancer and could cause delay in diagnosing it. If your symptoms continue in spite of your treatment, further investigations will be considered.

If you take **PRAZTEK** 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.

Children and adolescents

PRAZTEK must not be given to children as it is unknown if it is safe and effective for them *(see "Do not take PRAZTEK)*

Other medicines and PRAZTEK

Always tell your doctor or healthcare provider if you are taking any other medicines. (This includes all complementary or traditional medicines).

PRAZTEK may influence the effectiveness of other medicines, so tell your doctor if you are taking:

- Medicines such as ketoconazole, itraconazole and posaconazole (used to treat fungal infections) or erlotinib (used for certain types of cancer) because **PRAZTEK** may stop these and other medicines from working properly.
- Warfarin and phenprocoumon, which affect the thickening, or thinning of the blood. You may need further checks.
- Medicines used to treat HIV-infection, such as atazanavir.
- Methotrexate (used to treat rheumatoid arthritis, psoriasis, and cancer) – If you are taking methotrexate your doctor may temporarily stop your **PRAZTEK** treatment because pantoprazole can increase levels of methotrexate in the blood.
- Fluvoxamine (used to treat depression and other psychiatric diseases) – If you are taking fluvoxamine your doctor may reduce the dose.
- Mycophenolate mofetil – pantoprazole may reduce exposure to the active metabolite, mycophenolic acid.
- Rifampicin – medicine used to treat tuberculosis.
- St John's Wort – medicine used for depression.

PRAZTEK with food and drink

PRAZTEK should be taken either before or during breakfast without chewing or breaking them, swallow them whole with some water.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor, pharmacist, or other healthcare provider for advice before taking this medicine.
Safety in pregnancy and during lactation is unknown.

Driving and using machines

Pantoprazole does not adversely affect the ability to drive or use machines, however, adverse drug reactions such as dizziness and visual disturbances may occur. If affected, you should not drive or operate machines.

Sodium

This medicine contains less than 1 mmol sodium per tablet, that is to say essentially "sodium-free".

3. How to take PRAZTEK

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

Always take **PRAZTEK** exactly as your doctor or pharmacist has told. Check with your doctor or pharmacist if you are not unsure.

The recommended dose is **PRAZTEK 20 mg** to **PRAZTEK 40 mg** once a day depending on your condition. Your doctor will prescribe an appropriate dose according to your condition.

PRAZTEK tablets should be taken in the morning, swallowed whole with little water either before or during breakfast.
The gastro-resistant tablet should not be crushed because coating prevents pH sensitive degradation in the gut.

Use in children and adolescents

These tablets are not recommended for use in children due to limited data on safety and efficacy.

If you take more PRAZTEK than you should
In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. There are no known symptoms of overdose however as in any case of over dosage, treatment should be symptomatic and supportive measures should be utilised.

If you forget to take PRAZTEK
Do not take a double dose to make up for a forgotten dose. Take your next normal dose at the usual time.

If you stop taking PRAZTEK
Do not stop taking these tablets without first talking to your doctor or pharmacist. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

PRAZTEK can have side effects.

Not all side effects reported for **PRAZTEK** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **PRAZTEK**, please consult your health care provider for advice.

If any of the following happens to you, stop taking **PRAZTEK** and tell your doctor immediately, or go to the casualty department at your nearest hospital:

- severe allergic reaction to **PRAZTEK** with swelling of the mouth, tongue, or face and/or throat,
- difficulty to breathe or swallow,
- red lumpy skin rash (hives)
- dizziness which may result in collapse

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to PRAZTEK. 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:

- If you experience itching, right upper-belly pain, dark urine, yellow skin/eyes (jaundice), and unexplained flu-like symptoms (symptoms of liver damage that can lead to liver failure).
- If you develop severe flu-like symptoms followed by severe skin blisters with redness around them, or a peeling rash, hives and/or mouth sores. These are symptoms of Stevens-Johnson syndrome, a sometimes-fatal form of allergic skin disease.
- Any other severe skin eruption or swelling, especially in the face, near the eyes and mouth and sometimes in the throat, causing narrowing and difficulty with breathing that can be fatal.
- Problems with passing urine or if you pass urine more often than usual and develop a fever and generally feel unwell, or if you notice blood in your urine.
- Watery stool/runny tummy that does not go away, stomach pain and fever (See Section 2).

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

Tell your doctor if you notice any of the following:

The frequent side effects of **PRAZTEK** are:

- Digestive tract problems such as stomach pain, runny tummy (watery stools), constipation and bloating (gas).
- Headache.

Other less frequent effects include:

- nausea (feeling sick),
- vomiting,
- dry mouth,
- feeling abnormally weak and tired,
- generally feeling unwell,
- swollen hands and feet,
- hypersensitivity (allergic reactions) (see above).
- not seeing clearly,
- blood test results showing
- Impaired liver function, increase of certain fats in the blood (triglycerides, cholesterol), increase in bilirubin (formed when red blood cells breakdown),
- weight changes,
- increase in body temperature,
- joint pain,
- muscle pain,
- increased risk of wrist, hip, and spine bone breaks,
- feeling of dizziness or feeling like 'spinning',
- taste disorders,
- feeling down,
- not sleeping well,
- feeling confused or baffled,
- inflammation of the small, narrow spaces in the tissue of the kidney that can cause kidney problems,
- decrease in the blood of the number of red, white cells and platelets (pancytopenia)
- white blood cells (leukopenia) (may increase the risk of inflammation/infection),
- platelets (thrombocytopenia) (may increase risk of bruising or bleeding),
- sharp drop in circulating granular white blood cells (agranulocytosis) - an acute disease marked by high fever.
- Over sensitivity to sunlight.
- If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects
Reporting suspected adverse reactions after authorisation of the medicine is important. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "8.64 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications:https://www.sahpra.org.za/Publications/Index/5.

5. How to store PRAZTEK

Store at or below 25 °C (room temperature). Protect from light.
Keep the blisters in the carton until required for use.
Store in the original package in order to protect from light and moisture.
KEEP OUT OF THE REACH OF CHILDREN.
Do not store in a bathroom.
Do not use after the expiry date stated on the blister/carton
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 PRAZTEK 20 mg contains:
Each **PRAZTEK 20 mg** tablet contains 22,6 mg pantoprazole sodium sesquihydrate, equivalent to 20 mg pantoprazole base. Sugar free.

What PRAZTEK 40 mg contains
Each **PRAZTEK 40 mg** tablet contains 45,1 mg pantoprazole sodium sesquihydrate, equivalent to 40 mg pantoprazole base. Sugar free.

Other ingredients include:
Excipients: Mannitol, crospovidone, sodium carbonate anhydrous, calcium stearate, hydroxypropylmethyl cellulose, povidone, propylene glycol, titanium dioxide, iron oxide yellow, methacrylic acid copolymer, triethyl citrate.

What PRAZTEK looks like and contents of the pack

PRAZTEK 20 mg
Yellow, oval, biconvex, enteric-coated tablets plain on both sides.
PRAZTEK 40 mg
Yellow, oval, biconvex, enteric-coated tablets plain on both sides.

Blister pack.
Tablets are packed in cold form laminate, 25 µm OPA/45 µm Aluminium foil/60 µm PVC and Plain 25 µm Aluminium foil/6-8 gsm HSL as the blisting material.
Pack size for 20 mg: 28's
Pack size for 40 mg: 14's and 28's
Not all packs and pack size are necessarily marketed.

7. Holder of Certificate of Registration

MACLEODS PHARMACEUTICALS SA (PTY) LTD
Office Block 1, Bassonia Estate Office Park (East).
1 Cussonia Drive, Bassonia Rock, Ext. 12,
Alberton, South Africa

This leaflet was last revised in:
21 June 2022

Registration numbers
PRAZTEK 20 mg: 51/11.4.3/1124
PRAZTEK 40 mg: 51/11.4.3/1125

PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS: S4

PRAZTEK 20 mg en 40 mg gastro-beslande tablette
Pantoprasool natriumseskwihidraat
(Beval mannitol)

Lees hierdie hele inligtingstuk versorgvuldig deur voordat jy PRAZTEK begin neem:

- Hou hierdie inligtingstuk. Dit mag nodig wees dat jy dit weer moet lees.
- Vra asseblief jou dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer indien jy verdere vrae het
- **PRAZTEK** is vir jou persoonlik voorgeskryf, en jy moet nie jou medisyne met ander persone deel nie, Dit mag skadelik vir hulle wees, selfs al is hul simptome dieselfde as joune.

Wat in hierdie inligtingstuk is
1. Wat **PRAZTEK** is en waarvoor dit gebruik word
2. Wat jy behoort te weet voordat jy **PRAZTEK** neem
3. Hoe om **PRAZTEK** te neem
4. Moontlike newe-effekte
5. Hoe om **PRAZTEK** te bewaar
6. Inhoud van die pak en ander inligting

1. Wat PRAZTEK is en waarvoor dit gebruik word

PRAZTEK is 'n maklikheen 'protonpomp-inhibeerder', 'n medisyne wat die hoeveelheid suur wat in jou maag geproduseer word, verminder. Dit word gebruik vir die behandeling van suurverwante siektestoestande van die maag en ingewande.

PRAZTEK 20 mg word gebruik vir die behandeling van:
Ligte refluks esofagitis (ontsteking van die slukderm, 'n buis wat van die keel na die maag loop), en beheer van herhalende simptome in pasiënte met geneesde refluksiekte deur 'n op-aanvraag-regime te gebruik.
Langtermyn behandeling en voorkoming van terugvalrefluksiekte.
Maagsere wat veroorsaak word deur mediseyne genaamd NSAIM's (nie-steroïdale anti-inflammatoriese middels). Pantoprasool kan ook gebruik word om te keer dat maagsere vorm wanneer jy NSAIM's neem.
PRAZTEK 40 mg word gebruik vir die behandeling van:
Refluks esofagitis. In Ontsteking van jou slukderm (die buis wat jou keel met jou maag verbind) wat oppenet gaan met die terugstroming van maagsuur.
'n Infeksie met 'n bakterie genaamd *Helicobacter pylori* in pasiënte met duodenale ulkusse en maagsere in kombinasie met twee antibiotika (Eradikasie behandeling).
Maag- en duodenale ulkusse.
Zollinger-Ellison-sindroom, 'n siekte wat veroorsaak dat die maag te veel maagsuur sal gevolg het.

2. Wat jy behoort te weet voordat jy PRAZTEK neem

Moet nie PRAZTEK neem nie:

- indien jy hipersensitief (allergies) vir pantoprasool of vir enige van die ander bestanddele van **PRAZTEK** is (sien lys onder afdeling 6).
- indien jy ernstige lewerprobleme het.
- indien jy medisyne vir MIV gebruik soos atasenavir of nelfinavir (antiretrovirale middels): Hierdie medisyne mag dalk nie so goed teen jou MIV-infeksie werk, indien jy dit saam met **PRAZTEK** neem nie.
- **PRAZTEK** moet nie aan kinders gegee word nie, aangesien dit nie bekend is of dit veilig en effektief vir hulle is nie.

Waarskuwings en voorsorgmaatreëls
Verteltjou dokter of professionele gesondheidsorgwerker voordat jy **PRAZTEK** neem:
Neem spesiale sorg met **PRAZTEK**
- indien jy ernstige lewerprobleme het of indien jy al ooit in die verlede probleme met jou lewer gehad het. Hy sal jou lewerensieme meer gereeld nagaan, veral wanneer jy **PRAZTEK** as 'n langtermynbehandeling neem, in die geval van 'n verhoging in lewerensieme moet die behandeling gestaak word.
- indien jy verminderde liggaamstore, of risikofaktore vir verminderde vitamien B12 het en pantoprasool as langtermynbehandeling ontvang, aangesien pantoprasool tot 'n verminderde opname van vitamien B12 kan lei.
- indien jy MIV protease inhibeerders soos atasenavir of nelfinavir (vir die behandeling van MIV-infeksie) gelyklyding saam met pantoprasoolneem, vra jou dokter vir spesifieke advies.
- indien jy osteoporose het, of as jy kortikosteroïede neem (wat die risiko van osteoporose kan verhoog). Die neem van 'n protonpomp inhibeerder soos pantoprasool, veral oor 'n tydperk van meer as een jaar, kan jou risiko van fraktuur in die heup, pols of ruggraat effens verhoog.
- Indien jy vir langer as die maksimale dosis **PRAZTEK** is, is dit moontlik dat die vlakke van magnesium in jou bloed kan daal. Lae vlakke van magnesium kan gepaar word as moegheid, onwillekeurige spiersametrekkings, disorientasie, konvulsies, duiseligheid, verhoogde hartklop. Indien jy enige van hierdie simptome kry, vertel asseblief onmiddellik jou dokter. Lae vlakke van magnesium kan ook lei tot 'n afname in kalium- of kalsiumvlakke in die bloed. Jou dokter kan besluit om gereelde bloedtoetse uit te voer om jou magnesiumvlakke te monitor.
- Indien jy al ooit 'n velreaksie gehad het na behandeling met 'n middel wat maagsuur verminder, soos **PRAZTEK**.
- Indien jy 'n allergie op pus vol kry, veral in areas wat aan die son blootgestel is, moet jy dalk jou behandeling met **PRAZTEK** staak. Onthou om ook enige ander nadelige effekte, soos pyn in jou gewrigte, te noem.
- Indien jy 'n spesifieke bloedtoets (Chromogranien A) moet ondergaan.

Vertel onmiddellik jou dokter indien jy enige van die volgende simptome opmerk:

- Onbedoelde gewigsverlies
- braking, veral wanneer dit herhaal word
- braking van bloed; dit kan voorkom as donker koffie spikkels in jou braaksel
- jy sien bloed in jou stoelgang; wat swart of teeragtig in voorkoms kan wees
- jy merk bloed in jou urine op, 'n afname in uriene uitset, en koors
- sukkel om te sluk, of ervaar pyn tydens sluk
- borsaspyn
- maagpyn
- jy lyk bleek en voel swak (anemie)
- ernstige en/of aanhoudende diaree, aangesien **PRAZTEK** geassosieer is met 'n geringe toename in aansteeklike diarees.

Jou dokter kan moontlik besluit dat jy 'n paar toetse benodig om kwaadaardige siektes uit te sluit, omdat pantoprasool ook die simptome van kanker verlig, en vertraging in die diagnose daarvan kan veroorsaak. Indien jou simptome voortduur ten spyte van jou behandeling, sal verdere ondersoeke oorweeg word.

Indien jy **PRAZTEK** op 'n langtermynbasis neem (langer as 1 jaar), sal jou dokter jou waarskynlik onder gereelde toesig hou. Jy moet enige nuwe en buitengewone simptome en omstandighede aanmeld, wanneer jy jou dokter sien.

Kinders en adolessente
PRAZTEK moet nie aan kinders gegee word nie, aangesien dit onbekend is of dit veilig en doeltreffend vir hulle is (sien "Moet nie **PRAZTEK** neem nie).

Ander medisyne en PRAZTEK
Vertel altyd vir jou dokter of gesondheidsorgverskaffer indien jy enige ander medisyne neem, (Dit sluit komplementêre of tradisionele medisyne in).
PRAZTEK kan die doeltreffendheid van ander medisyne beïnvloed. As vertel vir jou dokter indien jy enige van die volgende neem:

- Medisyne soos ketokonasool, itrakonasool en posakonasool (wat gebruik word om swamboesmettings te behandel) of erlotinib (gebruik vir sekere soorte kanker) omdat **PRAZTEK** hierdie en ander medisyne kan verhoed om behoorlik te werk.
- Warfarien en fenprokoumon, wat die verdikking, of verdunning van die bloed beïnvloed. Jy sal dalk verdere ondersoeke nodig hê.
- Medisyne wat gebruik word om MIV-infeksie te behandel, soos atasenavir.
- Metotreksaat (gebruik om reumatoïede artritis, psoriase en kanker te behandel) – as jy metotreksaat neem, kan jou dokter jou behandeling met **PRAZTEK** tydelik staak, omdat pantoprasool die vlakke van metotreksaat in die bloed kan verhoog.
- Fluvoksamien (gebruik om depressie en ander psigiatriese siektes te behandel) – as jy fluvoksamien neem, kan jou dokter die dosis verminder.
- Mikofenolaatmofetil– pantoprasool kan blootstelling aan die aktiewe metaboliet, mikofenolsuur, verminder.
- Rifampisien—mediseyne wat gebruik word om tuberkulose te behandel.
- Sint Johanneskruid – mediseyne wat vir depressie gebruik word.

PRAZTEK met kos en vloeistowwe
PRAZTEK moet of voor of tydens ontbyt geneem word sonder om dit te kou of te breek, sluk dit heel, met 'n bietjie water.

Swangerskap en borsvoeding
Indien jy swanger is of borsvoed, vermoed dat jy moontlik swanger kan wees of beplan om 'n baba te hê, vra jou dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat jy hierdie medisyne neem.

Bestuur en gebruik van masjjinerie
Pantoprasool beïnvloed nie die vermoë om te bestuur of masjjiene te gebruik nadelig nie, maar nadelige geneesmiddelreaksies soos duiseligheid en visuele versteurings kan voorkom. Indien jy aangetas word, moet jy nie bestuur of masjjinerie hanteer nie.

Natrium
Hierdie medisyne bevat minder as 1 mmol natrium per tablet, dit wil sê in wese "natriumvry".

3. Hoe om PRAZTEK te neem

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

Neem altyd **PRAZTEK** presies soos jou dokter of apteker jou beveel het. Jy moet jou dokter of apteker nadpleeg indien jy nie seker is nie.

Die aanbevole dosis is **PRAZTEK 20 mg** tot **PRAZTEK 40 mg** een keer per dag, afhangende van jou toestand. Jou dokter sal 'n gepaste dosis volgens jou toestand voorskryf.

PRAZTEK tablette moet in die oggend geneem word, heelingesluk met 'n bietjie water, voor of tydens ontbyt.
Die gastro-beslande tablet moet nie fyngedruk word nie, want die deklaag verhoed pH-sensitiewe afbraak in die ingewande.

Gebruik in kinders en adolessente
As gevolg van beperkte data oor veiligheid en doeltreffendheid, word hierdie tablette nie aanbeveel vir gebruik in kinders nie.

Indien jy meer PRAZTEK neem as wat jy behoort te neem
In die geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of giftebeheersentrum. Daar is geen bekende simptome van oordosering nie, maar in enige geval van oordosering moet behandeling simptomaties wees en ondersteunende maatreëls moet gebruik word.

Indien jy vergeet om PRAZTEK te neem
Moet nie 'n dubbele dosis neem om op te maak vir 'n vergete dosis nie. Neem jou volgende normale dosis op die gewone tyd.

Indien jy staak om PRAZTEK te gebruik
Moet nie sonder om hierdie tablette te neem sonder om eers met jou dokter of apteker te praat nie. Indien jy enige verdere vrae het oor die gebruik van hierdie mediseyne, vra jou dokter of apteker.

4. Moontlike newe-effekte

PRAZTEK kan newe-effekte hê.
Nie alle newe-effekte wat vir **PRAZTEK** aangemeld is, is in hierdie inligtingstuk ingesluit nie. Sou jou algemene gesondheid verslag doen of indien jy enige ongewenste effekte ondervind terwyl jy **PRAZTEK** neem, raadpleeg asseblief jou gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, staak die gebruik van **PRAZTEK** en lig onmiddellik jou dokter in, of gaan na die ongevalle afdeling van jou naaste hospitaal

- ernstige allergiese reaksie op **PRAZTEK** met swelling van die mond, tong, of gesig en/of keel,
- moeilike asemhaling of sluk,
- rooi knoppetige veluitslag (galbulte)
- duiseligheid wat kan lei tot bewinsaantding

Hierdie is slegs baie ernstige newe-effekte. Indien jy dit het, het jy moontlik 'n ernstige allergiese reaksie op PRAZTEK gehad. Jy het moontlik dringende mediese aandag of hospitaalsake nodig.

Vertel onmiddellik jou dokter of gaan na die ongevalle afdeling by jou naaste hospitaal as jy enige van die volgende opmerk:

- Indien jy jeuk, regterbo-buikpyn, donker urine, geel velle (geelsug) en onverklaarbare griepagtige simptome (simptome van lewerskade wat tot lewerversaking kan lei) ervaar.
- Indien jy ernstige griepagtige simptome ontwikkel gevolg deur erge velblase met rooiheid rondom hulle, of 'n afskilferende uitslag, galbulte en/of mondseer. Hierdie is simptome van Stevens-Johnson-sindroom, 'n soms-dodelike vorm van allergiese velsiekte.
- Enige ander ernstige veluitbarsting of swelling, veral in die gesig, naby die oë en mond en soms in die keel, wat versuwing en probleme met asemhaling veroorsaak wat dodelik kan wees.
- Probleme met urinering of as jy meer gereeld as gewoonlik uitneer en koors ontwikkel en oor die algemeen onwel voel, of as jy bloed in jou urine opmerk.
- Waterige stoelgang/loperige maag wat nie weggaan nie, maagpyn en koors (Sien Afdeling 2).

Hierdie is slae ernstige newe-effekte. Jy het moontlik dringende mediese aandag of hospitaalsake nodig.

Vertel jou dokter indien jy enige van die volgende weerneem:

Die gereelde newe-effekte van **PRAZTEK** is:

- Spysverteringskanaalprobleme soos maagpyn, loperige maag (waterige stoelgang), hardlywigheid en opgeblaasenheid (winde).
- Hoofpyn.

Ander minder gereelde newe-effekte sluit in:

- naarheid (voel siek),
- braking,
- droë mond,
- voelsbenommenheid sterk en moeg,
- voel oor die algemeen onwel,
- geswelde hande en voete,
- hipersensitiwiteit (allergiese reaksies) (sien hierbo),
- kan nie duidelik sien nie,
- bloedtoetsresultate wat toon: ingekorte lewerfunksie, toename in sekere vette in die bloed (triglyseriede, cholesterol) en toename in bilirubien (gevorm wanneer rooibloedselle afbreek),
- veranderinge in gewig,
- toename in liggaamstemperatuur,
- gewrigspyn,
- soorspyn,
- verhoogde risiko van gebreek-, heup- en ruggraatbeen breuke,
- gevoel van duiseligheid of voel soos tol,
- smaakversteurings,
- voel neerslagtig,
- sleep nie lekker nie,
- verbysterd of verward voel,
- ontsteking van die klein, nou spasies in die weefsel van die nier wat nierprobleme kan veroorsaak,
- afname in die aantal van rooi-, wit selle en bloedplaatjies (pansitopenie) in die bloed,
- witbloedselle (leukopenie) (kan die risiko van infeksies/infeksie verhoog),
- bloedplaatjies (trombositopenie) (kan die risiko van bloeding verhoog),
- skerp daling in sirkulerende granulêre witbloedselle (agranulositose) – 'n akute siekte gekenmerk deur hoë koors.
- oorgevoeligheid teenoor sonlig.

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

Aanmelding van newe-effekte
Dit is belangrik om vermoedelike nadelige reaksies aan te meld, na goedkeuring van die medisyne. Gesondheidsorgverskaffers word gevra om enige vermoedelike nadelige reaksies aan SAHPRA te rapporteer deur middel van die "8.64 Adverse Drug Reaction Reporting Form", wat aanlyn gevind kan word onder SAHPRA se publikasies:https://www.sahpra.org.za/Publications/Index/5.

5. Hoe om PRAZTEK te bewaar

Bewaar by of bonade 25 °C (kamertemperatuur). Beskerm teen lig.
Hou die stuipstroke in die buitenste karton totdat dit benodig word vir gebruik.
BEWAAR ALLE MEDISYNE BUITE BEREIK VAN KINDERS.
Moet nie in 'n badkamer bêre nie.
Moet nie nadie vervaldatum, wat aangedring is op die stuipstrook/karton, gebruik nie.
Neem alle ongebruikte medisyne terug na jou apteker.
Moet nie ongebruikte medisyne in drains of rioolstelsels (bv. toilette) gooi nie.

6. Inhoud van die verpakking en ander inligting

Wat PRAZTEK 20 mg bevat:
Elke **PRAZTEK** 20 mg tablet bevat 22,6 mg pantoprasool natriumseskwihidraat, gelykstaande aan 20 mg pantoprasool basis. Suikervry.

Wat PRAZTEK 40 mg bevat
Elke **PRAZTEK** 40 mg tablet bevat 45,1 mg pantoprasool natriumseskwihidraat, gelykstaande aan 40 mg pantoprasool basis. Suikervry.

Ander bestanddele sluit in:
Hulpstowwe: Mannitol, kruspovidoon, anhidriese natriumkarbonaat, kalsiumstearaat, hidroksipropielmetielselulose, povidoon, propileenglikol, Standoksied, geel ysteroksied, metakrielsuurkopolimeer, trietielsitraat.

Hoe PRAZTEK lyk en inhoud van die verpakking
PRAZTEK 20 mg
Geel, ovaal, bikonvekse, enteriese-bedekte tablette, glad aan beide kante.
PRAZTEK 40 mg
Geel, ovaal, bikonvekse, enteries-bedekte tablette, glad aan beide kante.

Stuipverpakking:
Tablette word verpak in koue vorm laminaat, 25 µm OPA/45 µm aluminiumfoelie/60 µm PVC en gewone 25 µm aluminiumfoelie 6-8 gsm HSL as die dakmateriaal.
Verpakkingsgroottes vir 20 mg: 28's
Verpakkingsgroottes vir 40 mg: 14's en 28's
Nie alle verpakkings en verpakkingsgroottes word noodwendig bemark nie.

7. Houer van die Sertifikaat van Registrasie

MACLEODS PHARMACEUTICALS SA (Edms) Bpk
Kantoorblok 1, Bassonia Estate Kantoorpark (Oos),
Cussonia Weg 1, Bassonia Rock, Libbr. 12,
Alberton, SuidAfrika

Hierdie inligtingstuk was hersien in
21 Junie 2022

Registrasienommers
PRAZTEK 20 mg: 51/11.4.3/1124
PRAZTEK 40 mg: 51/11.4.3/1125

355 mm

435 mm

MASTER COPY

MACLEODS

PACKAGING RESEARCH & DEVELOPMENT

Restricted Circulation

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

1. Product: PRAZTEK 20/40 (Pantoprazole 20/40 mg)	
2. Country: South Africa (Private Market)	3. Packaging component: Patient Information
4. No. of Colours: 1 Colour	5. Pantone Shade No.: Black
6. Specification: 40 gsm bible paper	
7. Machine Layout No.: NA	8. Dimensions: 435 (L) x 355 (W) mm
9. Design / Style: Booklet type	10. Item code No.: PM03895601
11. Artwork has been made: Actual Size	12. Pharma code No.: 31636 mini
13. Barcode/NDC No: NA	14. Supersedes Item code No: NA
15. Revision no: 00	16. A/W File name: E:\ANDA Regulatory\South Africa\Pantoprazole\SA Private Market\PRAZTEK 20-40 PI & PIL -PM03895601.cdr
Approved By:	17. Location: Baddi

PRD	M.A. HOLDER	RAD	QC	PRODN	QA
24/08/22	Vanita Rajool	24/08/22	25/08/22	25/08/22	26/08/22

Note: 1. To follow overleaf checklist for approval of Artwork / Print proof.

QA 25/08/22

Instructions to Vendor :

1. Before processing, please ensure First pull out / Commercial supply should match with approved Artwork with respect to Design, Size, Fonts & Text.
2. Print proof to represent full printing area with Station Numbers.

FRM/CQA/021/04-01

Reason for revision :	Item code	Artwork Release Date	Artwork Implementation Date
1) New Artwork for South Africa (Private Market)	PM03895601		

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