PATIENT INFORMATION LEAFLET FOR PRAZOLOC OTC

SCHEDULING STATUS

S2

PRAZOLOC OTC (20 mg Enteric-coated tablets)

Pantoprazole

Contains: Mannitol 49,145 mg

Read all of this leaflet carefully because it contains important information for you

PRAZOLOC OTC is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use PRAZOLOC OTC carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share PRAZOLOC OTC with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.

You must see a doctor if your symptoms worsen or do not improve

What is in this leaflet

6. Contents of the pack and other information

1. What PRAZOLOC OTC is and what it is used for

PRAZOLOC OTC belongs to a group of medicines known as proton pump inhibitors. Proton pump inhibitors reduce the amount of acid secreted by the stomach.

PRAZOLOC OTC is indicated when intended for the temporary short-term relief of heartburn and hyperacidity for a maximum of 14 days.

2. What you need to know before you take PRAZOLOC OTC

Do not take PRAZOLOC OTC if you:

- Are allergic (hypersensitive) to pantoprazole or to any of the other ingredients in PRAZOLOC OTC (listed in **section 6**).
- Have severe impairment of your liver function.
- Are 12 years and younger, as safety has not been established in children.
- Are also taking atazanavir or nelfinavir for the treatment of Human Immunodeficiency Virus (HIV) infection (see other medicines and PRAZOLOC OTC**)**.

Warnings and Precautions

Take special care with PRAZOLOC OTC:

- if you have impaired kidney function
- if you are taking warfarin (medicine that reduces the risk of blood clotting)
- if you have liver disease
- if you have low levels of magnesium in your blood

- if you are currently being treated or have a history of any malignancies (cancer or tumour) in the stomach area, or you think you have signs of stomach cancer (symptoms include weight loss, dark stools, loss of appetite, feeling full or a sensation of a lump in your stomach)
- if you have a history of a Vitamin B12 deficiency and receive long-term treatment (e.g. longer than 3 years) with PRAZOLOC OTC. As with all acid reducing agents, PRAZOLOC OTC may lead to a reduced absorption of vitamin B12
- use of PRAZOLOC OTC taken to prevent gastroduodenal ulcers, induced by nonselective non-steroidal anti-inflammatory drugs (NSAIDs) should only be taken by patients who require continued NSAID treatment and have an increased risk to develop gastrointestinal complications
- if you develop diarrhoea that does not improve (contact your doctor or healthcare professional as soon as possible) because PRAZOLOC OTC has been associated with a small increase in infectious diarrhoea
- if you are over 50 years of age or when you take PRAZOLOC OTC for a long period of time or in high doses (it may cause a low magnesium level in the body and cause an increase in risk of bone fractures in the hip, wrist or spine)
- if you have or had a bone fracture in the hip, wrist or spine due to low magnesium
- if you are taking HIV protease inhibitors such as atazanavir (for the treatment of HIV-infection) at the same time as pantoprazole, ask your doctor for specific advice
- 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

PRAZOLOC OTC. Remember to also mention any other ill-effects like pain in your joints

- if you take PRAZOLOC OTC on a long-term basis (longer than 1 year), your doctor will probably keep you under regular surveillance. You should report any new and exceptional symptoms and circumstances whenever you see your doctor
- if you are on pantoprazole, as in PRAZOLOC OTC, for more than three months, it is possible that the levels of magnesium in your blood may fall. Low levels of magnesium can be seen as fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness or increased heart rate. If you get any of these symptoms, please tell your doctor promptly. Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood. Your doctor may decide to perform regular blood tests to monitor your levels of magnesium
- if there is a decrease in the amount that you urinate or if you have blood in your urine
- if you are due to have a specific blood test (Chromogranin A) PRAZOLOC OTC treatment should be stopped for at least 5 days before Chromogranin A (CgA) measurements are taken and may require a further test 14 days after stopping therapy with PRAZOLOC OTC.

Other medicines and PRAZOLOC OTC

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

Some medicines that may be affected by PRAZOLOC OTC are:

- medicines to thin your blood, such as warfarin. PRAZOLOC OTC may alter the effect of these medicines so your healthcare provider will want to monitor how well your blood clots
- certain medicines used to treat fungal infections, such as ketoconazole PRAZOLOC OTC may reduce their absorption
- atazanavir, a compound found in anti-HIV medicines. PRAZOLOC OTC may reduce the blood levels of this medicine. You should not use PRAZOLOC OTC concurrently with atazanavir (see Do not take PRAZOLOC OTC)
- methotrexate (high doses used in the treatment of certain cancers). PRAZOLOC OTC may increase the levels of this medicine and possibly lead to methotrexate toxicity
- fluvoxamine (used to treat depression and other psychiatric diseases) – if you are taking fluvoxamine your doctor may reduce the dose
- St John's wort (Hypericum perforatum) (used to treat mild depression).
- the active ingredient, pantoprazole, is metabolised by certain liver enzymes, which may interact with other medicines or compounds which are also metabolised by these enzymes.

PRAZOLOC OTC with food, drink and alcohol

PRAZOLOC OTC may be taken with food, or on an empty stomach, preferably in the morning (see **"How to take Prazoloc OTC "**).

Pregnancy, breastfeeding and fertility

You should not take PRAZOLOC OTC if you are pregnant or breastfeeding your baby.

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

Safety in pregnancy and breastfeeding has not been established.

There is no data on fertility in humans with PRAZOLOC OTC.

Driving and using machinery

PRAZOLOC OTC may cause dizziness, drowsiness or double vision, which may impair your ability to drive or operate machinery. You should refrain from driving or operating machinery until you know how PRAZOLOC OTC affects you.

PRAZOLOC OTC contains sodium and mannitol

PRAZOLOC OTC contains sodium. Your doctor will take this into account if you are on a sodium-controlled diet. PRAZOLOC OTC contains mannitol and may have a laxative effect.

3. How to take PRAZOLOC OTC

Always take PRAZOLOC OTC exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. Do not share medicines prescribed for you with other people.

PRAZOLOC OTC should preferably be taken in the morning. Swallow the tablet whole with a little water either before or during breakfast. Do not crush, break, or chew the tablet.

The maximum daily dose is 20 mg per day and the maximum treatment is for a period of 14 days.

No dosage adjustment is necessary if you are an elderly person.

No dosage adjustment is required if you have impaired kidney function.

If you have liver problems you should not take more than the daily dose of one PRAZOLOC OTC per day.

Children

Safety and efficacy in children have not been established.

If you take more PRAZOLOC OTC than you should:

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

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

If you forget to take PRAZOLOC OTC

Always take PRAZOLOC OTC as prescribed. If you miss a dose, take it as soon as you remember. If you do not remember the missed dose until the next dose is due, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for forgotten individual doses.

4. Possible Side Effects

PRAZOLOC OTC can have side effects.

Not all side effects reported for PRAZOLOC OTC are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking PRAZOLOC OTC, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop using PRAZOLOC OTC and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching.

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

- stomach pain (severe)
- fever, rash, and enlarged kidneys sometimes with painful urination and lower back pain (serious inflammation of the kidneys), possibly leading to kidney failure
- blistering, loosening, peeling or redness of skin, Stevens-Johnson syndrome or other serious skin disorders such as Lyell-Syndrome, Erythema multiforme, (begins with flu-like symptoms, followed by a painful red or purplish rash that spreads and blisters), drug rash with eosinophilia and systemic symptoms (DRESS) which is a type of drug allergy which can occur as a reaction to a large variety of medications
- yellow skin colour and/or yellow eyes, black tarry stools (symptoms of liver disease)

- blurred vision.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- diarrhoea or constipation, abdominal pain, flatulence
- headache.

Less frequent side effects:

- numbers of white cells in your blood
- high concentration of fatty products in the blood, increased body temperature
- trouble in sleeping, depression, disorientation
- dizziness, distortion or complete lack of the sense of taste
- nausea and/or vomiting, dry mouth, bloating, stomach pain and discomfort
- other skin conditions
- The feeling that your environment is moving or spinning or ringing in the ears.
- pain in joints or muscles, fracture of the hip, wrist or spine
- swelling and enlargement of breasts in men
- feeling of weakness, fatigue, malaise (feeling bad), swelling of the hands and feet
- muscle rigidness or stiffness.

The following side effects have been reported but the frequency for them to occur is not known:

- inflammation in the large bowel, that causes persistent watery diarrhoea
- low levels of salt or magnesium or calcium in the blood

- hallucination, confusion
- feeling of tingling, prickling, pins and needles, burning sensation or numbness
- muscle spasm as a consequence of electrolyte disturbance
- a type of kidney problem (acute interstitial nephritis). Some people who take proton pump inhibitor (PPI) medicines, including PRAZOLOC OTC, may develop a kidney problem called acute interstitial nephritis, that can happen at any time during treatment with PPI medicines. Call your doctor right away if you have a decrease in the amount that you usually urinate or if you have blood in your urine.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "**Adverse drug reaction and quality problem reporting form**", found online under SAHPRA's publications: https://www.sahpra.org.za/document/adverse-drug-reactions-and-quality-problemreporting-form/ or to Cipla Medpro (Pty) Ltd. by e-mail: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free). By reporting side effects, you can help provide more information on the safety of PRAZOLOC OTC.

5. How to store PRAZOLOC OTC

Store at or below 25 °C. Protect from light.

Store all medicines out of reach of children.

Keep the blisters in the outer carton until required for use.

Do not use after the expiry date stated on the packaging material.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems, for example toilets.

6. Contents of the pack and other information

What PRAZOLOC OTC contains

The active substance is pantoprazole.

The other ingredients are calcium stearate, crospovidone (CLM), ferric oxide (yellow), hydroxypropyl cellulose, hypromellose, mannitol, methacrylic acid-Ethyl acrylate copolymer, propylene glycol, sodium carbonate, titanium dioxide, and triethyl citrate.

What PRAZOLOC OTC looks like and contents of the pack

Yellow coloured, capsule shaped, biconvex tablet plain on both sides.

Blister strips of 7, 10 or 14 tablets packed in a carton.

Holder of Certificate of Registration

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