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 pharmacist if you need more information or advice.
- You must see your doctor if your symptoms worsen or do not improve after 14 days.

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

PRAZOLOC OTC should not be used for the treatment of mild gastro-intestinal complaints, such as nervous dyspepsia (indigestion due to stress or anxiety).

Before you start treatment with PRAZOLOC OTC, you may have to go for an endoscopic examination (swallow the scope). During this procedure a small piece of tissue may be taken from the stomach, oesophagus, or duodenum for examination under a microscope. This is called a biopsy and biopsies are necessary to rule out the possibility of cancer of the stomach or oesophagus. It is important that you inform your doctor if you recently experienced significant unintentional weight loss, recurrent vomiting, pain with swallowing, vomiting of blood or a substance resembling coffee grounds, or passed dark, foul-smelling, tarry stools. Responding to treatment with PRAZOLOC OTC does not rule out the presence of stomach or oesophageal cancer.

Performing an endoscopic examination with biopsy prior to treatment will enable your doctor to make a timely diagnosis of cancer and to institute appropriate treatment.

Daily treatment with any acid-blocking medicine, such as PRAZOLOC OTC, over a long period of time (e.g. longer than 3 years) may lead to malabsorption of vitamin B_{12}. Inadequate absorption of vitamin B_{12} may lead to anaemia (shortage of red blood cells). Please inform your doctor as soon as possible if you experience weakness, tiredness or light-headedness, rapid heartbeat and breathing, pale skin, sore tongue, easy bruising or bleeding, bleeding gums, or stomach upset.

You may have to go for blood tests to monitor your liver enzyme levels while you are taking PRAZOLOC OTC**.**

While on treatment of PRAZOLOC OTC you may be at risk of developing a kidney disorder called interstitial nephritis, causing the inside of your kidneys to become inflamed. This condition may progress to renal failure as it is not necessarily reversed when treatment with PRAZOLOC OTC is stopped (see **"Possible side-effects"**)

Use of PRAZOLOC OTC as preventative of gastroduodenal ulcers, induced by non-selective non-steroidal anti-inflammatory drugs (NSAIDs) should be restricted to patients who require continued NSAID treatment and have an increased risk to develop gastro-intestinal complications.

Other medicines and PRAZOLOC OTC

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

PRAZOLOC OTC

- may increase or decrease the absorption of certain medicines of which absorption is pH-dependent e.g., ketoconazole (medicines used as antifungals)

- the active ingredient called pantoprazole is metabolised by certain liver enzymes. It may interact with medicines or compounds which are also metabolised by these enzymes.
- taken together with anti-clotting medicines such as warfarin has no effect on the clotting of blood but may influence the time it takes for blood to clot. Your doctor will monitor this when PRAZOLOC OTC therapy is initiated, taken irregularly, or discontinued.
- Decrease the concentrations of atazanavir and nelfinavir (medication used in the treatment of HIV/AIDS)

There are no interactions with concomitantly administered antacids.

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

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 professional for advice before taking PRAZOLOC OTC, as safety and efficacy in pregnancy and breastfeeding have not been established.

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.

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.

If you take more PRAZOLOC OTC than you should:

In the event of an overdosage, or if someone else has taken your medicine by mistake, you, or this other person, may experience any of the side-effects listed below.

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

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 taking PRAZOLOC OTC and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Those that occur less frequently:
    - Allergic reactions presenting with tightness of the chest, coughing, dizziness, fast heartbeat, hives, itching, puffiness or swelling of the eyelids, swelling of the face, lips or tongue, or severe swelling of the whole body, skin rash, and/or collapse.

- Shortness of breath or wheezing.
- Yellow discolouration of the skin or whites of the eyes accompanied by loss of appetite, nausea, and pain over the liver area, as this may indicate inflammation of the liver.
- Blisters on the skin.

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 hospitalization.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Those that occur frequently:

- Diarrhoea (loose stools) accompanied by stomach pain or cramps, loss of appetite and chills or fever.
- Coughing, sneezing, sore throat, skin ulcers and other signs of infection, as this may be due to low white cell counts.
- Pinpoint red spots on the skin, easy bruising or bleeding from the gums, as this may be due to low platelet counts.
- Confusion.
- Seeing or hearing things that are not real.
- Loss of vision with or without severe eye pain.
- Breath with a musty or sweet odour accompanied by confusion,

mental fogginess, personality or mood changes, poor concentration, abnormal movements or shaking of the hands or arms, agitation, excitement, seizures/convulsions, slurred speech, slowed or sluggish movement, and/or loss of consciousness, as these symptoms may be due to liver damage.

- Those that occur less frequently:
    - Pins and needles.
    - Blurred vision.
    - Ulcers or sores inside the mouth or on the lips.
    - Any other skin rash, including a skin rash in areas exposed to the sun.
    - Struggling to pass urine, increased frequency and volume or urination, painful urination or change in the colour of your urine.
    - Interstitial nephritis (Kidney disease causing the inside of the kidney to become inflamed) which may progress to renal failure as it is not necessarily reversed when treatment is stopped.

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

Tell your doctor if you notice any of the following:

- Those that occur frequently:
    - Sleeplessness or trouble sleeping.
    - Headache.
    - Flatulence (gas), constipation, or stomach pain.

- Fatigue or tiredness.

- Those that occur less frequently:
  - Depression, agitation, or sleepiness.
  - Dizziness.
  - The feeling that your environment is moving or spinning, or ringing in the ears.
  - Swelling of the hands or feet.
  - Vomiting, or dry mouth.
  - Joint or muscle pain.
  - Impotence.
  - Breast enlargement (in males).
  - Generally feeling unwell, or increased sweating.
  - Taste disturbances

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 "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8 or 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. (Ref 2)

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

CIPLA MEDPRO (PTY) LTD.

Building 9

Parc du Cap

Mispel Street

Bellville

7530

RSA

Customer Care: 080 222 6662

This leaflet was revised in

03/02/2023

REGISTRATION NUMBER

43/11.4.3/1145

Access to the corresponding Professional Information

To access corresponding Professional Information, scan the QR Code below.

PLACE HOLDER: The QR Code to be generated and included after approval.

Namibia: NS2 10/11.4.3/0406

References

1. Annotated Professional Information Prazoloc OTC, authorisation date 30 September 2016, revision dated TBA
2. Current SAHPRA Guideline for Professional Information for Human Medicines (Categories A and D), dated July 2019.