Module 1.3.2 Patient Information Leaflet

Information for the Patient about

PRAZOLOC 20 / 40

Read all of this leaflet carefully before you start taking PRAZOLOC.

- **Keep this leaflet, you may need to read it again.**
- **If you have further questions, please ask your doctor or your pharmacist.**
- **PRAZOLOC 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.**

SCHEDULING STATUS

S4

PROPRIETARY NAME (AND PHARMACEUTICAL FORM)

PRAZOLOC 20 (Enteric-coated tablets)

PRAZOLOC 40 (Enteric-coated tablets)

WHAT PRAZOLOC CONTAINS

The active substance is pantoprazole.

PRAZOLOC 20: Each enteric-coated tablet contains pantoprazole sodium sesquihydrate equivalent to 20 mg pantoprazole

PRAZOLOC 40: Each enteric-coated tablet contains pantoprazole sodium sesquihydrate equivalent to 40 mg pantoprazole

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

PRAZOLOC 20: contains sugar (mannitol) 49,145 mg per tablet

PRAZOLOC 40: contains sugar (mannitol) 98, 290 mg per tablet

WHAT PRAZOLOC IS USED FOR

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

PRAZOLOC 20 is used:

- To improve symptoms (such as heartburn, regurgitation of stomach acid and pain on swallowing) and promote healing of mild gastro-oesophageal reflux disease (GORD) (reflux of stomach acid into the oesophagus).
- For long-term management and prevention of relapse of GORD.

- To prevent stomach lesions and indigestion caused by non-selective non-steroidal anti-inflammatory drugs (NSAIDs) used to treat pain and inflammation (see **Take special care with PRAZOLOC**).

PRAZOLOC 40 is used:

- For the short-term treatment of duodenal ulcer (ulcer located in the first part of the small bowel, also known as the duodenum).
- To treat stomach (gastric) ulcer.
- To treat inflammation of the oesophagus due to acid reflux (known as reflux oesophagitis).
- For the treatment of Zollinger-Ellison Syndrome, a disorder associated with the production of too much stomach acid.

BEFORE YOU TAKE PRAZOLOC

Do not take PRAZOLOC if you:

- Are allergic (hypersensitive) to pantoprazole or to any of the other ingredients in **PRAZOLOC** (see **WHAT PRAZOLOC CONTAINS**).
- 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 **Taking other medicines with PRAZOLOC**).

Take special care with PRAZOLOC:

PRAZOLOC 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**, 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** 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.

If you have to use NSAIDs for extended periods of time, your doctor may prescribe **PRAZOLOC** to prevent a stomach or duodenal ulcer (see **WHAT PRAZOLOC IS USED FOR**). Your doctor will decide whether you qualify for treatment with **PRAZOLOC**.

Daily treatment with any acid-blocking medicine, such as **PRAZOLOC**, 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**.

While on treatment with **PRAZOLOC**, 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** is stopped (see **POSSIBLE SIDE EFFECTS**).

Taking PRAZOLOC with food and drink:

PRAZOLOC may be taken with food, or on an empty stomach, preferably in the morning (see **HOW TO TAKE PRAZOLOC**).

Pregnancy and breastfeeding:

The safety and efficacy of PRAZOLOC in pregnancy and breastfeeding have not been established.

If you are pregnant or breastfeeding your baby while taking PRAZOLOC, please consult your doctor, pharmacist or other healthcare professional for advice.

Driving and using machinery:

PRAZOLOC 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** affects you.

Important information about some of the ingredients of PRAZOLOC:

PRAZOLOC contains maltitol. If you have been told that you have an intolerance to some sugars, you should not take **PRAZOLOC**.

Taking other medicines with PRAZOLOC:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, use of PRAZOLOC with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

Please discuss the use of the following medicines in combination with **PRAZOLOC** with your doctor or pharmacist, as you may require a dosage adjustment or special precautions:

- Atazanavir and nelfinavir for the treatment of HIV infection (see **Do not take PRAZOLOC**).
- Warfarin, a blood thinner, as warfarin in combination with **PRAZOLOC** may increase the risk of bleeding. You will have to go for blood tests when treatment with warfarin is started or stopped, or if you take your warfarin irregularly.
- Ketoconazole for fungal infections or other medicines whose absorption is dependent on the pH (acidity level) of the stomach contents. Please speak to your doctor or pharmacist if you are unsure.

There are no interactions with concomitantly administered antacids.

HOW TO TAKE PRAZOLOC

Always take PRAZOLOC 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 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.**

Depending on your diagnosis, your doctor will decide on the dosage of **PRAZOLOC** and how long treatment will last. The usual dosage varies between 20 mg and 40 mg per day and treatment usually lasts for approximately 4 weeks. However, shorter courses may be sufficient in some patients, while others may require longer treatment durations or higher doses.

If you feel that your symptoms are not improving after four weeks of taking **PRAZOLOC** as instructed, it is recommended that you return to your doctor.

If you have the impression that the effect of **PRAZOLOC** is too strong or too weak, please discuss this with your doctor or pharmacist.

If you take more PRAZOLOC 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:

Always take **PRAZOLOC** 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.

POSSIBLE SIDE EFFECTS

PRAZOLOC can have side effects.

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

Serious side effects that you, or a family member, should report to your doctor as a matter of urgency include:

- 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.

- 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.
- 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.
- 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.
- Blisters on the skin.
- Fever, rash and enlarged kidneys, sometimes with painful

urination and lower back pain (serious inflammation of the kidneys), since this could lead to kidney failure (see **Take special care with PRAZOLOC**).

Side effects that you should report to your doctor as soon as possible include:

- Those that occur frequently:
    - Diarrhoea (loose stools) accompanied by stomach pain or cramps, loss of appetite and chills or fever.
- Those that occur less frequently:
    - Pins and needles.
    - Blurred vision.
    - Taste disturbances.
    - 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.

Please report the following side effects to your doctor if they continue or become bothersome:

- 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.

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

STORAGE AND DISPOSING OF PRAZOLOC

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

KEEP 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.

PRESENTATION

PRAZOLOC 20: Blister strip of 10 tablets packed in a carton as 10's and 30's.

PRAZOLOC 40: Blister strip of 10 tablets packed in a carton as 30's.

IDENTIFICATION

PRAZOLOC 20: Yellow coloured, capsule shaped, biconvex tablet plain on both sides.

PRAZOLOC 40: Yellow coloured, capsule shaped, biconvex tablet with "40" imprinting on one side and plain on the other side.

REGISTRATION NUMBERS

PRAZOLOC 20: 43/11.4.3/1147

PRAZOLOC 40: 43/11.4.3/1148

NAME AND ADDRESS OF REGISTRATION HOLDER

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RSA

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