Patient Information Leaflet

Information for the Patient about

PRAZOLOC 40 IV

Read all of this leaflet carefully before PRAZOLOC 40 IV is administered to you:

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

SCHEDULING STATUS

S4

PROPRIETARY NAME (AND PHARMACEUTICAL FORM

PRAZOLOC 40 IV (Powder for solution for I.V. injection/infusion)

WHAT PRAZOLOC 40 IV CONTAINS

The active substance in **PRAZOLOC 40 IV** is pantoprazole sodium.

Each **PRAZOLOC 40 IV** vial contains pantoprazole sodium sesquihydrate equivalent to 40 mg pantoprazole.

WHAT PRAZOLOC 40 IV IS USED FOR

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

PRAZOLOC 40 IV is used to treat various conditions associated with the production of too much stomach acid:

- The short-term treatment of duodenal ulcer (i.e. ulcer located in the first part of the small bowel, also known as the duodenum), gastric ulcer (stomach ulcer) and reflux oesophagitis (inflammation of the oesophagus caused by reflux of stomach acid).
- Duodenal ulcers associated with *Helicobacter pylori* (a bacterium that grows in the stomach) infection, in which instance you may have to take antibiotics in combination with **PRAZOLOC 40 IV**.
- Zollinger-Ellison syndrome, a disorder associated with abnormally high levels of the hormone gastrin, which in turn stimulates the stomach to produce too much acid.

PRAZOLOC 40 IV is given intravenously (into a blood vessel or vein) to patients who cannot take oral medicines.

BEFORE YOU RECEIVE PRAZOLOC 40 IV

Do NOT receive PRAZOLOC 40 IV if you:

- Are allergic (hypersensitive) to any of the ingredients in **PRAZOLOC 40 IV**.
- Have severe impairment of liver function. Please speak to your doctor if you are unsure.
- Are also taking atazanavir or nelfinavir (see **"Receiving**

PRAZOLOC 40 IV with other medicines").

It is not known whether **PRAZOLOC 40 IV** is safe and effective when used in children.

Take special care with PRAZOLOC 40 IV:

If your liver function deteriorates, treatment with **PRAZOLOC 40 IV** will be stopped.

You should not receive **PRAZOLOC 40 IV** for mild stomach complaints, such as nervous dyspepsia (indigestion).

Before you start treatment with **PRAZOLOC 40 IV**, your doctor will examine you for the presence of cancer (malignancy) of the stomach or oesophagus. This is usually done with an endoscopic examination (swallowing the scope) during which a small piece of tissue is taken from the stomach or oesophagus (biopsy) for examination under a microscope. Responding to treatment with **PRAZOLOC 40 IV** does not rule out the presence of stomach or oesophageal cancer.

Daily treatment with any acid-blocking medicines, such as **PRAZOLOC 40 IV**, over a long period of time (e.g. longer than 3 years) may lead to

malabsorption of cyanocobalamin (vitamin B_{12}). **PRAZOLOC 40 IV** is usually only given over the short-term.

While on treatment of **PRAZOLOC 40 IV** 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 40 IV** is stopped (see **"POSSIBLE SIDE-EFFECTS"**).

Receiving PRAZOLOC 40 IV with food and drink:

You may receive **PRAZOLOC 40 IV** without regard to meals.

Pregnancy and breastfeeding:

It is not known whether it is safe to use **PRAZOLOC 40 IV** during pregnancy or while you are breastfeeding your baby.

If you are pregnant or breastfeeding your baby while receiving PRAZOLOC 40 IV, please consult your doctor, pharmacist or other healthcare professional for advice.

Driving or using machinery:

PRAZOLOC 40 IV may cause dizziness or disturbances in vision. You should refrain from operating machinery or driving until you know how **PRAZOLOC 40 IV** affects you.

Receiving PRAZOLOC 40 IV with other medicines:

If you are taking medicines on a regular basis, including complementary or traditional medicines, concomitant use of such medicines with PRAZOLOC 40 IV may cause undesirable interactions. Please consult your doctor or pharmacist, or other healthcare professional for advice.

Please discuss the use of the following medicines or substances in combination with **PRAZOLOC 40 IV** with your doctor:

- Atazanavir or nelfinavir for the treatment of Human Immunodeficiency Virus (HIV) infection (see **"Do NOT receive PRAZOLOC 40 IV if you"**).
- Anticoagulants (blood thinning medicines), such as warfarin, as you may have to go for additional blood tests when you start or stop treatment.

HOW TO RECEIVE PRAZOLOC 40 IV

PRAZOLOC 40 IV will be administered into one of your veins over a period of 2 to 15 minutes. It is administered to patients who cannot take

oral medicines. The usual dosage is one vial (40 mg) per day. Your doctor may adjust this dosage, depending on your diagnosis.

Treatment with **PRAZOLOC 40 IV** usually lasts up to 7 days, after which you will be given the same oral dose. Total duration of treatment is dependent on your diagnosis and whether or not you are able to take oral medicines.

If you suffer from a duodenal ulcer associated with *Helicobacter pylori* infection (see **"WHAT PRAZOLOC 40 IV IS USED FOR"**), you will also receive treatment with antibiotics to clear the infection.

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 impaired liver function, your doctor may decide to adjust your dosage.

If you have the impression that the effects of **PRAZOLOC 40 IV** are too strong or too weak, please speak to your doctor.

POSSIBLE SIDE EFFECTS

PRAZOLOC 40 IV can have side effects.

Not all side effects reported for PRAZOLOC 40 IV are included in this leaflet. Should your general health worsen while receiving PRAZOLOC 40 IV, please consult your doctor, pharmacist or other healthcare professional for advice.

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

- Those that occur less frequently:
    - Swelling of the face, lips, or tongue, shortness of breath, wheezing, hives, or itching.
    - Fever, chills, coughing, skin ulcers, bleeding from the gums, easy bruising, blood in the urine, and tiredness or weakness.
    - Speech disorders, muscle stiffness, struggling with movement, and pins and needles.
    - Loss of vision, double vision or any other vision disturbances.
    - Tightness of the chest, difficult breathing.
    - Severe stomach pain with bloating of the stomach and severe vomiting.
    - Yellow discolouration of the skin or whites of the eyes, pain over the liver area, with or without alteration in consciousness.
    - Any skin rash with blister formation.
    - Struggling to pass urine, pain in the flank, or cloudy or

discoloured urine.

- Those that occur with unknown frequency:
    - Pinpoint red spots on the skin.

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

- Those that occur frequently:
    - Loose stools with or without vomiting.
- Those that occur less frequently:
    - Feeling hungry, sweaty or shaky.
    - Migraine.
    - A sensation that you or the world is spinning.
    - Chest pain.
    - Swelling of the feet or ankles.
    - Breast enlargement in males.
    - Pain or swelling at the site of injection.
    - Painful urination or pain over the bladder area.
- Those that occur with unknown frequency:
    - Skin rash in areas exposed to the sun.
    - 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.

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

- Those that occur frequently:
    - Headache.
    - Tiredness, weakness or fatigue.
- Those that occur less frequently:
    - Runny or blocked nose, sore throat, or coughing.
    - Anxiety, agitation, sleepiness or drowsiness, or struggling to sleep.
    - Dizziness.
    - Ringing in the ears.
    - Nausea, stomach pain, constipation, flatulence (gas), belching, indigestion, increased salivation, or taste disturbances.
    - Hair loss.
    - Joint, back, or neck pain.
    - Impotence.
    - Increased sweating.
    - Generally feeling unwell.
- Those that occur with unknown frequency:
    - Depression.
    - Dry mouth.
    - Muscle pain.

Please tell your doctor or pharmacist of any other undesirable effects you think may be due to receiving **PRAZOLOC 40 IV**, especially if not mentioned in this leaflet.

STORAGE AND DISPOSING OF PRAZOLOC 40 IV

The centre where you receive treatment will store and dispose of **PRAZOLOC 40 IV** on your behalf.

Freeze dried powder: store at or below 25 °C.

For single use only.

Any unused portion of the reconstituted/diluted solution must be discarded.

Protect from light and moisture.

Keep in the outer carton until required for use.

KEEP ALL MEDICINES OUT OF REACH AND SIGHT OF CHILDREN.

PRESENTATION OF PRAZOLOC 40 IV

10 ml capacity USP type 1 flint clear, colourless, tubular glass vial with a 20 mm bromobutyl grey rubber stopper sealed with a 20 mm white aluminium flip-off, tear-off seal containing lyophilised powder and packed in a carton.

IDENTIFICATION OF PRAZOLOC 40 IV

Off-white cake or powder.

Reconstituted final product: clear colourless solution free from visible particles.

REGISTRATION NUMBER

44/11.4.3/0305

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

CIPLA MEDPRO (PTY) LTD.

Building 9, Parc du Cap

Mispel Street

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RSA

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