PATIENT INFORMATION LEAFLET
PEPLOC RANGE

SCHEDULING STATUS

S4

PEPLOC 20 mg, tablets

PEPLOC 40 mg, tablets

Pantoprazole

PEPLOC contains sugar (sugar alcohol — mannitol 70,50 and 141,0 mg/tablet)

PEPLOC is essentially 'sodium free'.

Read all of this leaflet carefully before you start taking PEPLOC

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

1. What PEPLOC is and what it is used for

Pantoprazole is a proton pump inhibitor used to treat certain conditions in which there is too much acid in

the stomach.

PEPLOC 40 mg is used for:

- the treatment of duodenal ulcers, gastric ulcers and heartburn
- the treatment of Zollinger-EIlison syndrome (a rare disorder that causes tumours in the pancreas and part of the small intestine (duodenum) and ulcers in the stomach and duodenum).

PEPLOC 20 mg is used for:

- the treatment of symptoms of heartburn, pain during swallowing and to heal mild gastro-oesophageal reflux disease (GORD), also known as acid reflux disease
- the long-term management and prevention of reoccurrence of GORD.

2. What you need to know before you take PEPLOC

Do not take PEPLOC:

- if you are hypersensitive (allergic) to pantoprazole or any of the other ingredients of PEPLOC 20 or 40 mg tablets (see section 6)
- if your liver function is impaired
- PEPLOC should not be given to children
- if you are taking atazanavir (a medicine used in the treatment of HIV).

Warnings and precautions

Take special care with PEPLOC:

Inform your doctor:

- if you have impaired kidney function
- if you are taking warfarin, a 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 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 B_{12} deficiency and receive long-term treatment (e.g. longer than 3 years) with PEPLOC. As with all acid reducing agents, PEPLOC may lead to a reduced absorption of vitamin B_{12}
- use of PEPLOC taken to prevent gastroduodenal ulcers, induced by nonselective nonsteroidal 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 PEPLOC has been associated with a small increase in infectious diarrhoea
- if you are over 50 years of age or when you take PEPLOC 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 PEPLOC. Remember to also mention any other ill-effects like pain in your joints
- if you take PEPLOC 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 PEPLOC, 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) PEPLOC 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 PEPLOC.

Other medicines and PEPLOC

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

Some medicines that may be affected by PEPLOC are:

- medicines to thin your blood, such as warfarin. PEPLOC may alter the effect of these medicines so your healthcare provider will want to monitor how well your blood clots
- PEPLOC may reduce the blood levels of atazanavir, a compound found in anti-HIV medicines. You should not use PEPLOC concurrently with atazanavir (see Do not take PEPLOC)
- PEPLOC may reduce the absorption of certain medicines used to treat fungal infections, such as ketoconazole
- PEPLOC may increase the levels of methotrexate (high doses used in the treatment of certain cancers) 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.

PEPLOC with food and drink

The recommended once daily dose of PEPLOC should be taken before a meal, preferably in the morning.

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 provider for advice before using PEPLOC.

The recommended once daily dose of PEPLOC should be taken before a meal, preferably in the morning.

Safety in pregnancy and breastfeeding has not been established.

There is no data on fertility in humans with PEPLOC.

Driving and using machines

PEPLOC may cause blurred vision or dizziness which may impair your ability to drive or operate machinery.

It is not always possible to predict to what extent PEPLOC may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which PEPLOC affects them.

PEPLOC contains sodium

Your doctor will take this into account if you are on a sodium-controlled diet.

PEPLOC contains less than 1 mmol sodium (0,023 g) per dose, that is to say essentially 'sodium free'.

3. How to take PEPLOC

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

Always take PEPLOC exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The tablets should be swallowed whole. Do not crush, break or chew the tablet.

It may take several days before PEPLOC begins to relieve your symptoms. To help relieve your symptoms, antacids may be taken with PEPLOC tablets, unless your doctor has told you not to use them.

The recommended dosage will be different for different patients.

Adults:

Duodenal ulcer: One tablet of PEPLOC 40 mg **once** daily in the morning for 2 - 4 weeks.

Your doctor may combine your treatment with antibiotics if the bacteria *H. pylori* infection is present.

Stomach ulcer: One tablet of PEPLOC 40 mg once daily in the morning for 4 - 8 weeks.

Reflux oesophagitis: One tablet of PEPLOC 40 mg once daily in the morning for 4 - 8 weeks.

Zollinger-Ellison syndrome: You should start treatment with a daily dose of 80 mg of PEPLOC.

Your doctor can increase the dose above 80 mg.

Mild gastro-oesophageal reflux disease (GORD): One tablet of PEPLOC 20 mg in the morning for 4 weeks.

Your doctor will decide if you should continue treatment for another 4 weeks.

Long-term management and prevention of relapse in GORD: A maintenance dose of one PEPLOC 20 mg tablet per day is recommended.

Your doctor may increase the dose to 40 mg if your GORD symptoms worsen.

After healing, you can continue with the 20 mg dosage regimen.

Children:

Safety and efficacy in children has not been established.

Your doctor will tell you how long your treatment with PEPLOC will last. Do not stop treatment early because your condition may worsen.

If you have the impression that the effect of PEPLOC is too strong or too weak, tell your doctor or pharmacist.

If you take more PEPLOC 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 PEPLOC

If you missed a dose, take it as soon as you remember. If it is almost time for your next dose, skip the missed dose and continue to take the tablet at the usual time. Do not take a double dose to make up for

forgotten individual doses.

If you stop taking PEPLOC

Take PEPLOC tablets for the full time of treatment, even if you begin to feel better. Do not stop treatment early because your condition may worsen.

4. Possible side effects

PEPLOC can have side effects.

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

If any of the following happens, stop using PEPLOC 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 PEPLOC. 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:

- 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:

- low numbers of white cells in your blood
- high concentration of fatty products in the blood, increased body temperature
- dizziness, distortion or complete lack of the sense of taste
- nausea and/or vomiting, dry mouth, bloating, stomach pain and discomfort
- other skin conditions
- 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.

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 PEPLOC, 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 any side effects to SAHPRA via the online service for adverse drug reaction reporting by using either of the following the links: https://www.sahpra.org.za/Publications/Index/8 or https://www.sahpra.org.za/document/adverse-drug-reactions-and-quality-problem-reporting-form/.

By reporting side effects, you can help provide more information on the safety of PEPLOC. You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za, to ensure safety of the product.

5. How to store PEPLOC

Store all medicines out of reach of children.

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

Keep blisters in carton until required for use.

Do not use after the expiry date stated on the 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 PEPLOC contains:

The active substance is pantoprazole.

Each PEPLOC 20 mg tablet contains pantoprazole sodium sesquihydrate equivalent to 20 mg pantoprazole.

Each PEPLOC 40 mg tablet contains pantoprazole sodium sesquihydrate equivalent to 40 mg pantoprazole.

The other ingredients are

Tablet cores:

Carmellose sodium, colloidal anhydrous silica, magnesium stearate, mannitol, sodium carbonate anhydrous, sodium starch glycolate type A

Coating:

Hypromellose, methacrylic acid-ethyl acrylate copolymer, propylene glycol, titanium dioxide, triethyl citrate, yellow iron oxide.

What PEPLOC looks like and contents of the pack

PEPLOC 20 mg: Orangish, biconvex and oval gastro-resistant tablet.

Diameter: 4,7 mm x 9,0 mm.

PEPLOC 40 mg: Orangish, biconvex and oval gastro-resistant tablet.

Diameter: 6,1 mm x 11,7 mm.

PEPLOC 20 mg and 40 mg are packed in aluminium-polyamide- PVC/aluminium blister strips, with 28 or 30 tablets are packed in an outer carton.

Holder of Certificate of Registration

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