

**PATIENT INFORMATION LEAFLET  
PEPLOC RANGE**

**Scheduling Status:**

**S4**

**Proprietary name, Strength and Pharmaceutical Form:**

**Peploc 20 mg** tablets

**Peploc 40 mg** tablets

**Read all of this leaflet carefully before using PEPLOC 20 mg or 40 mg**

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

**1. WHAT PEPLOC CONTAINS**

Each **Peploc 20 mg** tablet contains pantoprazole sodium sesquihydrate equivalent to 20 mg pantoprazole as the active ingredient. Each **Peploc 40 mg** tablet contains pantoprazole sodium sesquihydrate equivalent to 40 mg pantoprazole as the active ingredient. **Peploc** tablets contain the following inactive ingredients: carmellose sodium, colloidal anhydrous silica, hypromellose, magnesium stearate, mannitol, methacrylic acid-ethyl acrylate copolymer (1:1), sodium carbonate anhydrous, propylene glycol, sodium starch glycolate type A, triethyl citrate and the colourants yellow iron oxide (E172) and titanium dioxide (E171).

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#### 2. WHAT PEPLOC 40 mg 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.
- Zollinger-Ellison Syndrome (a rare disorder that causes tumours in the pancreas and 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-esophageal reflux disease (GERD) also known as acid reflux disease.
- The long-term management and prevention of reoccurrence of GERD.

#### 3. BEFORE YOU TAKE PEPLOC

**Do not take PEPLOC:**

- If you are hypersensitive (allergic) to pantoprazole or any of the other ingredients of **PEPLOC 20 mg or 40 mg** tablets.
- If your liver function is impaired.
- **PEPLOC** should not be given to children.

**Take special care with PEPLOC:**

- Inform your doctor:
  - If you have impaired kidney function,
  - If you are taking atazanavir (a medicine used in the treatment of HIV)
  - if you are taking warfarin
- Tell your doctor if you are currently being treated or have a history of any malignancies in the stomach area.
- If you have a history of a Vitamin B12 deficiency.

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- **PEPLOC** may be associated with an increased risk of *Clostridium difficile* associated diarrhoea (CDAD) (you may develop diarrhoea that does not improve). Contact your doctor or healthcare professional as soon as possible.

**Taking PEPLOC tablets with food or drink:**

Take **PEPLOC** tablets immediately before a meal, preferably in the morning.

**PEPLOC** tablets may be taken with food or on an empty stomach. **PEPLOC** tablets should be swallowed whole with a little water.

**Pregnancy and breastfeeding:**

If you are pregnant or breastfeeding your baby while taking **PEPLOC**, please consult your doctor, pharmacist or other health care professional for advice before taking this medicine.

Safety in pregnancy and breastfeeding has not been established.

**Driving and using machinery:**

**PEPLOC tablets** may cause blurred vision or dizziness. You should refrain from driving or using machinery until you know how **PEPLOC** affects you.

**Using other medicines with PEPLOC tablets:**

Always tell your healthcare professional if you are taking any other medicine.

(This includes complementary or traditional medicines.)

**PEPLOC** may reduce the absorption of certain medicines used to treat fungal infections, such as ketoconazole.

**4. HOW TO USE PEPLOC Tablets**

Always take **PEPLOC** exactly as your doctor has instructed you. You should check with your doctor if you are unsure. If you have the impression that the effect of **PEPLOC** is too strong or too weak, talk to your doctor or pharmacist.

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

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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.

Take **PEPLOC** Tablets for the full time of treatment, even if you begin to feel better.

The recommended dosage will be different for different patients.

Duodenal ulcer: One tablet of **PEPLOC 40 MG** once daily in the morning for 2 to 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 to 8 weeks.

Reflux oesophagitis: One tablet of **PEPLOC 40 MG** once daily in the morning for 4 to 8 weeks.

Zollinger-Ellison Syndrome: You should start their treatment with a daily dose of 80 mg of **PEPLOC**. Your doctor can increase the dose above 80mg.

Mild gastro-oesophageal reflux disease (GERD): One tablet of **PEPLOC 20** 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 GERD: A maintenance dose of one **PEPLOC 20** tablet per day is recommended. Your doctor may increase the dose to **40 mg** if your GERD symptoms worsen. After healing, you can continue with the **20 mg** dosage regimen.

**If you take more PEPLOC than you should:**

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre. Take this leaflet and any remaining tablets with you, so that the doctor knows what the person has 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 you next

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dose, skip the missed dose and continue to take the tablet at the usual time. Do not take a double or larger dose to make up for the forgotten individual doses.

### 5. 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 side effects while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

If the following side effects occur, they may need medical attention.

*Check with your doctor as soon as possible if any of the following side-effects occur:*

- Stomach pain (severe)
- Blistering, loosening, peeling or redness of skin
- Yellow skin colour and/ or yellow eyes
- Large hive-like swellings of eyelids, face, lips, mouth and/or tongue
- Pain in joints or muscles
- Blurred vision
- Black tarry stools

You may experience other side-effects that usually do not need medical attention.

However, check with your doctor if any of the following side-effects continue or are bothersome:

- Headache
- Nausea and/or vomiting
- Diarrhoea or constipation
- Dizziness
- Muscle rigidity or stiffness

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

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**6. STORING AND DISPOSING OF PEPLOC**

- Store at or below 25 °C. Store blister in the outer carton until required for use
- Do not use the tablets after the expiry date printed on the label or blister
- Return all unused medicine to your pharmacist
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets)
- KEEP ALL MEDICINES OUT OF REACH OF CHILDREN