

**PATIENT INFORMATION LEAFLET
PEPLOC IV**

SCHEDULING STATUS:

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

PEPLOC IV lyophilised powder for injection (each vial contains pantoprazole sodium equivalent to 40 mg pantoprazole).

Please read this leaflet carefully before receiving PEPLOC IV injection.

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

2. WHAT PEPLOC IV IS USED FOR:

Pantoprazole is a proton pump inhibitor used to treat certain conditions in which the stomach produces too much acid.

PEPLOC IV is used:

- For the short-term treatment of stomach ulcers, intestinal ulcers and heartburn.
- As an injection in patients who cannot swallow medicines to be taken orally.
- In combination with appropriate anti-bacterial medicines (antibiotics) if the intestinal ulcer is associated with an infection caused by the *Helicobacter pylori* bacterium.
- For the treatment of Zollinger-Ellison syndrome, a condition in which the pancreas and small intestine, produce too much of the hormone, gastrin.

3. BEFORE YOU RECEIVE PEPLOC IV:**Do not receive PEPLOC IV:**

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- If you are hypersensitive (allergic) to pantoprazole or any of the other ingredients of **PEPLOC IV** (see **WHAT PEPLOC IV CONTAINS**).
- If you have severe liver disease (see **HOW PEPLOC IV WILL BE ADMINISTERED TO YOU** and **Take special care with PEPLOC IV**).
- If you are a child, i.e. 12 years old or younger.
- If you are currently taking a medicine used to treat viral infections, called atazanavir (see **Using other medicines with PEPLOC IV**).

Take special care with PEPLOC IV:

- Your doctor will prescribe **PEPLOC IV** after thorough examination to show the absence of other diseases with the same symptoms and might make use of special tests to confirm the diagnosis.
- **PEPLOC IV** must be administered by a qualified healthcare professional, with an injection into a blood vessel and by no other route.
- The use of **PEPLOC IV** may be associated with an increased risk of *Clostridium difficile* associated diarrhoea. Your doctor will consider a diagnosis of *Clostridium difficile* associated diarrhoea if you develop diarrhoea that does not improve while taking **PEPLOC IV**.
- **PEPLOC IV** may affect the ability to safely drive or use machinery (see **Driving and using machinery**).

Pregnancy and breast feeding:

If you are pregnant or breastfeeding your baby while receiving **PEPLOC IV**, please tell your doctor, pharmacist or other health care professional.

You should not receive **PEPLOC IV** if you are pregnant, suspecting you are pregnant or planning to become pregnant.

You should not receive **PEPLOC IV** if you are breastfeeding.

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Driving and using machinery:

PEPLOC IV may cause vertigo (being off balance with blurred vision), dizziness or hypokinesia (difficulty in movement). You should therefore refrain from driving or using machinery until you know how **PEPLOC IV** affects you.

Using other medicines with PEPLOC IV:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **PEPLOC IV** with these medicines may cause undesirable interactions.

Tell your doctor or pharmacist if you are taking any other medicines, including any you have bought at your pharmacy, supermarket or health food shop. Please consult your doctor, pharmacist or other healthcare professional for advice.

PEPLOC IV may interact with other medicines broken down and eliminated by the body in a similar way as **PEPLOC IV**. Although there is no evidence of clinically important interactions between **PEPLOC IV** and these medicines, interactions with the following groups of compounds should be considered:

- Medicines used to treat anxiety, mood disorders and epilepsy (diazepam, phenytoin, carbamazepine).
- Medicines used to treat inflammation, pain and fever (diclofenac, naproxen, piroxicam, antipyrine).
- Medicines used to treat heart conditions (digoxin, metoprolol, nifedipine, warfarin).
- Medicines used to treat respiratory diseases such as asthma (theophylline).
- Medicines used to treat diabetes (glibenclamide).
- Oral contraceptives.
- Alcohol (ethanol).

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- Caffeine as found in certain medicines, coffee and tea.

If you are also treated with anti-clotting medicines such as warfarin, acenocoumarol or phenprocoumon, your doctor will monitor your blood clotting time when **PEPLOC IV** treatment is started, stopped, or taken irregularly.

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

Antacids do not alter the function of **PEPLOC IV** and you may therefore use antacids concomitantly.

PEPLOC IV may reduce the blood levels of atazanavir, a compound found in anti-viral medicines also containing ritonavir. **PEPLOC IV** may therefore not be given to you, if you are also taking medicines containing atazanavir and ritonavir (see **Do not receive PEPLOC IV**).

4. HOW PEPLOC IV WILL BE ADMINISTERED TO YOU:

PEPLOC IV will be administered to you by an injection into a blood vessel.

Your doctor will decide on the correct dose and duration of the treatment based on your condition.

Speak to your doctor if you have any questions about the amount and duration of your treatment with **PEPLOC IV**.

5. POSSIBLE SIDE-EFFECTS:

PEPLOC IV may have side-effects.

Not all side effects reported for PEPLOC IV are included in this leaflet.

Should your general health worsen while taking PEPLOC IV, please consult your doctor, pharmacist or other health care professional for advice.

The following side-effects may require immediate medical attention:

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- Severe allergic reactions and allergic shock (associated with throat swelling, an itchy rash, and a drop in blood pressure).
- Rapid swelling of the skin and mucous membranes (linings of your mouth, nose, throat), multiple skin lesions due to an allergic reaction and inflammation of the skin, hives, skin rash and itching.
- Yellowing of the skin (jaundice) as a result of the liver failing its normal function, increase in liver enzymes, inflammation of the liver, confusion, an altered level of consciousness and coma as a result of a failing liver.
- Skin rash, blistering of the skin.
- Loss of vision.
- Difficulty in breathing.
- Stomach flu and diarrhoea.

The following side-effects may also occur:

- Difficulty in talking, dizziness, difficulty in moving, feeling off balance.
- Anxiety, confusion, dizziness, trouble in sleeping.
- Blurred vision, a ringing sound in the ears.
- Migraine, headache.
- Drowsiness, pins-and-needles / sleeping limbs, taste disturbances.
- Infections of the nose, throat, sinuses, lungs and coughing.
- Stomach pain, burping, constipation, indigestion, feeling bloated, nausea, increased production of saliva, vomiting.
- Dry mouth, inflammation of the lining of the mouth.
- Itching, increased sensitivity to sunlight, hair loss, sweating.
- Joint pain, back pain, stiff muscles, neck pain, muscle pain.
- Bladder infections.

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- Depression which may subside when stopping therapy, restlessness, abnormal sensing of your environment.
- Chest pain, a skin reaction at the site of injection, weakness, flu-like symptoms, pain.
- Fever, swelling of hands and feet, tiredness, feeling of discomfort.
- Other infections.

The following side-effects can only be identified and confirmed by your doctor:

- Low numbers of white cells in your blood.
- High blood sugar levels, high concentration fatty products in the blood, increased body temperature.
- Inflammation of the pancreas, disorders of the lower end of the large bowel.
- Bladder infections, kidney disease.
- Low levels of salt in the blood.

6. STORING AND DISPOSING OF PEPLOC IV:

- Lyophilised powder: Store at or below 25 °C
- Protect from light
- The product must be kept in the outer carton until required for use
- Reconstituted solution: Store at or below 25 °C for 12 hours. Discard any unused portion
- Do not use the after the expiry date printed on the carton
- Return all unused medicine to your pharmacist
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets)
- Keep medicines out of reach and sight of children