

PATIENT INFORMATION LEAFLET
PEPLOC OTC

SCHEDULING STATUS:

S2

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

PEPLOC OTC tablets

Read all of this leaflet carefully because it contains important information for you.

PEPLOC OTC is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use **PEPLOC OTC** carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share **PEPLOC OTC** with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 7-14 days.

1. WHAT PEPLOC OTC CONTAINS

The active substance is pantoprazole.

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

The other ingredients are carmellose sodium, colloidal anhydrous silica, hypromellose, magnesium stearate, mannitol, methacrylic acid-ethyl acrylate copolymer, propylene glycol, sodium carbonate anhydrous, sodium starch glycolate type A, triethyl citrate and the colourants yellow iron oxide and titanium dioxide.

Contains mannitol.

2. WHAT PEPLOC OTC IS USED FOR

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

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PEPLOC OTC is indicated for:

- The temporary short-term relief of heartburn and hyperacidity for a maximum daily dose of 20 mg and a maximum treatment period of 14 days.

3. BEFORE YOU TAKE PEPLOC OTC

Do not take PEPLOC OTC:

- If you are hypersensitive (allergic) to pantoprazole or any of the other ingredients of **PEPLOC OTC**.
- If your liver function is impaired.
- **PEPLOC OTC** should not be given to children.
- If you are taking atazanavir (a medicine used in the treatment of HIV).

Take special care with PEPLOC OTC:

- Inform your doctor:
 - if you have impaired kidney function
 - if you are taking warfarin (medicine that reduces the risk of blood clotting)
 - if you have liver disease
 - if you have low levels of magnesium in your blood.
- Tell your doctor if you are currently being treated or have a history of any malignancies (cancer or tumour) in the stomach area.
- If you have a history of a Vitamin B12 deficiency.
- If you develop diarrhoea that does not improve, contact your doctor or healthcare professional as soon as possible.
- If you are over 50 years of age or when you take **PEPLOC OTC** 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.

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Taking PEPLOC OTC with food or drink:

PEPLOC OTC tablets 20 mg daily should be taken before a meal, preferably in the morning.

Pregnancy and breastfeeding:

You should not take **PEPLOC OTC** if you are pregnant or breastfeeding your baby.

If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or other healthcare professional for advice before taking **PEPLOC OTC**. Safety in pregnancy and breastfeeding has not been established.

Driving and using machinery:

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

Important information about some of the ingredients of PEPLOC OTC:

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

PEPLOC OTC contains mannitol and may have a laxative effect.

Taking other medicines with PEPLOC OTC:

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

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

PEPLOC OTC may reduce the blood levels of atazanavir, a compound found in anti-HIV medicines. You should not use **PEPLOC OTC** concurrently with atazanavir (see **Do not take PEPLOC OTC**).

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4. HOW TO TAKE PEPLOC OTC

Do not share medicines prescribed for you with any other person. The tablets should be swallowed whole. Do not crush, break or chew the tablet.

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

If you take more PEPLOC OTC than you should:

When an overdose is suspected contact your doctor or pharmacist as soon as possible. If neither is available, seek help at the nearest hospital or poison centre. Take this leaflet and any remaining tablets with you, so that the doctor knows what you have taken.

If you forget to take a dose of PEPLOC OTC:

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 or larger dose to make up for the forgotten individual doses.

5. POSSIBLE SIDE EFFECTS

PEPLOC OTC can have side effects.

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

If any of the following happens, stop taking **PEPLOC OTC** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth, tongue or throat, which may cause difficulty in swallowing or breathing

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- rash or itching.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **PEPLOC OTC**. 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:

- ♦ Stomach pain (severe)
- ♦ Blistering, loosening, peeling or redness of skin
- ♦ 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:

- ♦ Muscle rigidity or stiffness, pain in joints or muscles
- ♦ Headache, dizziness
- ♦ Nausea and/or vomiting, diarrhoea or constipation, abdominal pain, flatulence
- ♦ Confusion, trouble in sleeping, depression, hallucination, disorientation
- ♦ Swelling and enlargement of breasts in men
- ♦ Feeling of weakness, fatigue, malaise (feeling bad), swelling of the hands and feet
- ♦ Fracture of the hip, wrist or spine.

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

- Low numbers of white cells in your blood
- High concentration of fatty products in the blood, increased body temperature. Low levels of salt or magnesium or calcium in the blood
- Other skin conditions
- Kidney disease.

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

6. STORING AND DISPOSING OF PEPLOC OTC

- Store at or below 25 °C. Protect from moisture.
- 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)
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.