

PATIENT INFORMATION LEAFLET
PEPLOC OTC

SCHEDULING STATUS

S2

PEPLOC OTC, 20 mg tablets

Pantoprazole

PEPLOC OTC contains sugar alcohol (mannitol 70,50 mg/tablet)

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 healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 14 days.

What is in this leaflet

1. What PEPLOC OTC is and what it is used for
2. What you need to know before you take PEPLOC OTC
3. How to take PEPLOC OTC
4. Possible side effects
5. How to store PEPLOC OTC
6. Contents of the pack and other information

1. What PEPLOC OTC 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.

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PEPLOC OTC is used 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.

2. What you need to know 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 tablets (see section 6)
- 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).

Warnings and precautions

Take special care with PEPLOC OTC:

- 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
- 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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- if there is a decrease in the amount that you urinate or if you have blood in your urine.

Other medicines and PEPLOC OTC

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 OTC are:

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

PEPLOC OTC with food and drink

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

Pregnancy, breastfeeding and fertility

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

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a 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 machines

PEPLOC OTC may cause blurred vision or dizziness.

It is not always possible to predict to what extent PEPLOC OTC 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 OTC affects them.

PEPLOC OTC contains sodium and mannitol

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.

3. How to take PEPLOC OTC

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

Always take PEPLOC OTC exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

The tablets should be swallowed whole with water.

Do not crush, break or chew the tablet.

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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 tablets, unless your doctor has told you not to use them.

The usual dose is one 20 mg tablet once a day, for a maximum of 14 days.

Children:

Safety and efficacy in children have not been established.

If you take more PEPLOC OTC 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 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 forgotten individual doses.

4. 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 healthcare provider for advice.

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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 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 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)
- 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 disorder (begins with flu-like symptoms, followed by a painful red or purplish rash that spreads and blisters)
- 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.

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Less frequent side effects:

- low numbers of white cells in your blood
- high concentration of fatty products in the blood, increased body temperature
- trouble in sleeping, depression, disorientation
- 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
- muscle riggedness or stiffness
- 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.

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
- hallucinating, feeling confused
- feeling of tingling, prickling, pins and needles, burning sensation or numbness.

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

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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 following the link:

<https://www.sahpra.org.za/Publications/Index/8> or

<http://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 OTC. You can also send an email directly to the company, pharmacovigilance@pharmadynamcs.co.za to ensure safety of the product.

5. How to store PEPLOC OTC

Store all medicines out of reach of children.

Store at or below 25 °C.

Protect from moisture.

Keep blisters in carton until required for use.

Do not use 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 or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What PEPLOC OTC contains

The active substance in each PEPLOC OTC tablet is pantoprazole sodium sesquihydrate equivalent to 20 mg pantoprazole.

The other ingredients are:

Tablet cores:

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

Tablet coating:

Hypromellose, methacrylic acid-ethyl acrylate copolymer, propylene glycol, titanium dioxide (E171), triethyl citrate, yellow iron oxide (E172).

What PEPLOC OTC looks like and the contents of the pack

PEPLOC OTC: Orangish, biconvex and oval gastro-resistant tablet. Diameter: 4,7 mm x 9,0 mm.

PEPLOC OTC tablets are packed in aluminium-polyamide- PVC/aluminium blister strips.

7 or 14 tablets are packed in an outer carton.

Holder of Certificate of Registration

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