PATIENT INFORMATION LEAFLET

PEPLOC OTC

SCHEDULING STATUS:

S2

PEPLOC OTC 20 mg tablets

Pantoprazole

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

Essentially 'sodium free'.

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

PATIENT INFORMATION LEAFLET

PEPLOC OTC

1. What PEPLOC OTC is and what it is used for

PEPLOC OTC contains pantoprazole, one of a group of medicines called proton pump inhibitors used to treat certain conditions in which there is too much acid in the stomach.

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 (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 human immunodeficiency virus (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, 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 B12 deficiency and receive long-term treatment (e.g. longer than 3 years) with PEPLOC OTC. As with all acid reducing agents, PEPLOC OTC may lead to a reduced absorption of vitamin B_{12}
- use of PEPLOC OTC taken to prevent gastroduodenal ulcers, induced by nonselective non-steroidal 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 OTC has been associated with a small increase in infectious diarrhoea
- 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
- 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 OTC. Remember to also mention any other ill-effects like pain in your joints
- if you take PEPLOC OTC 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 OTC, 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 OTC 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 OTC.

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).
- 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 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

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

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 OTC.

Safety in pregnancy and breastfeeding has not been established.

There is no data on fertility in humans with PEPLOC OTC.

Driving and using machines

PEPLOC OTC 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 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

PEPLOC OTC contains sodium.

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

3. How to take PEPLOC OTC

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

Always take/use PEPLOC OTC exactly as described in this leaflet or as your doctor, pharmacist or nurse have 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.

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.

Adults:

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 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 using PEPLOC OTC, please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, stop using 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 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
- 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 rigidness or stiffness.

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 OTC, 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 or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website.

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@pharmadynamics.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 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 OTC contains

The active substance is pantoprazole.

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

The other ingredients are

Tablet cores:

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 contents of the pack

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

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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This leaflet was last revised in

17 January 2025

Registration number(s)

A43/11.4.3/0344

NAM:

NS1 18/11.4/0081