PEPLOC OTC

SCHEDULING STATUS S2

1. NAME OF THE MEDICINE
PEPLOC OTC 20 mg tablets.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each PEPLOC OTC tablet contains pantoprazole sodium sesquihydrate equivalent to pantoprazole 20 mg.

PEPLOC OTC contains sugar (mannitol 70,50 mg/tablet).
Essentially 'sodium free'.
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Tablets.
Orangish, biconvex and oval gastro-resistant tablets.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
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.

4.2 Posology and method of administration
Posology
PEPLOC OTC should be taken in the morning. The recommended oral dose is 20 mg of PEPLOC OTC per day.

Special populations
Elderly patients
No dosage adjustment is necessary in the elderly.

Impaired renal and liver function
No dosage adjustment is required in the presence of impaired renal function. A daily dose of 20 mg PEPLOC OTC should not be exceeded in patients with mild to moderately severe liver impairment (see sections 4.4 and 5.2).

Paediatric population
Safety and efficacy in children have not been established (see section 4.3).

Method of administration
PEPLOC OTC should be swallowed whole with a little water either before or during breakfast.

4.3 Contraindications
PEPLOC OTC is contraindicated in:
- hypersensitivity to pantoprazole or to any of the ingredients of PEPLOC OTC (see section 6.1)
- safety and efficacy in children have not been established
- severely impaired liver function (see section 4.4)
- co-administration with atazanavir (see section 4.5).

4.4 Special warnings and precautions for use
Co-administration with anticoagulants
The response to anticoagulants such as warfarin may be affected by any concomitant medication. It is therefore good practice to monitor the patient with additional PT (prothrombin time)/INR (international normalised ratio) determinations when PEPLOC OTC is initiated, discontinued or taken irregularly. Changes in absorption should be observed when medicines whose absorption is pH-dependent, e.g. ketoconazole, are taken concomitantly.

Gastric malignancy
Prior to treatment, or in the presence of any alarm symptom (e.g. significant unintentional weight loss, recurrent vomiting, dysphagia, haematemesis, anaemia or melaena) the possibility of malignancy of a gastric ulcer or a malignant disease of the oesophagus should be excluded, as the treatment with PEPLOC OTC may alleviate the symptoms of malignant ulcers and can thus delay diagnosis.

Diagnosis of reflux oesophagitis
Diagnosis of reflux oesophagitis should be confirmed by endoscopy.

Clostridium difficile associated diarrhoea (CDAD)
PEPLOC OTC may be associated with an increased risk of *Clostridium difficile* associated diarrhoea (CDAD). A diagnosis of CDAD should be considered for patients taking PEPLOC OTC who develop diarrhoea that does not improve. Patients should use the lowest dose and shortest duration of PEPLOC OTC therapy appropriate to the condition being treated.

Gastrointestinal infections caused by bacteria
Treatment with pantoprazole may lead to a slightly increased risk of gastrointestinal infections caused by bacteria such as *Salmonella* and *Campylobacter* or *C. difficile* especially in hospitalised patients. Pantoprazole, like all proton pump inhibitors (PPIs), might be expected to increase the counts of bacteria normally present in the upper gastrointestinal tract. This diagnosis should be considered for diarrhoea that does not improve (see section 4.8).

Hypomagnesaemia
Severe hypomagnesaemia has been rarely reported in patients treated with proton pump inhibitors (PPIs) like PEPLOC OTC for at least three months, and in most cases for a year. Serious manifestations of hypomagnesaemia such as fatigue, tetany, delirium, convulsions, dizziness and ventricular arrhythmia can occur but they may begin insidiously and be overlooked. Hypomagnesaemia may lead to hypocalcaemia and/or hypokalaemia (see section 4.8). In most affected patients, hypomagnesaemia (and hypomagnesaemia associated hypocalcaemia and/or hypokalaemia) improved after magnesium replacement and discontinuation of the PPI.
For patients expected to be on prolonged treatment or who take PPIs with digoxin or medicines that may cause hypomagnesaemia (e.g. diuretics), health care professionals should consider measuring magnesium levels before starting PPI treatment and periodically during treatment.

Bone fractures
The use of PEPLOC OTC may be associated with an increased risk of bone fractures in the hip, wrist or spine. This effect has been reported mostly in people taking high doses, on long-term treatment, and in those who were 50 years and older or in presence of other recognised risk factors.
Observational studies suggest that proton pump inhibitors may increase the overall risk of fracture by 10 - 40%. Some of this increase may be due to other risk factors. Patients at risk of osteoporosis should receive care according to current clinical guidelines and they should have an adequate intake of vitamin D and calcium.

Hepatic impairment
In patients with severe liver impairment the liver enzymes should be monitored regularly during treatment with PEPLOC OTC. In the case of a rise of the liver enzymes, PEPLOC OTC should be discontinued.

Mild gastrointestinal complaints
PEPLOC OTC should not be used for mild gastrointestinal complaints such as nervous dyspepsia.

Vitamin B12 absorption
PEPLOC OTC, over a long period of time (e.g. longer than 3 years), may lead to malabsorption of vitamin B12 caused by hypo- or achlorhydria.
This should be considered in patients with reduced body stores or risk factors for reduced vitamin B12 absorption on long-term therapy or if respective clinical symptoms are observed.

Co-administration with nonsteroidal anti-inflammatory drugs (NSAIDs)
The use of PEPLOC OTC as a preventive of gastroduodenal ulcers induced by non-selective nonsteroidal anti-inflammatory drugs (NSAIDs) should be restricted to patients who require continued NSAID treatment and have an increased risk to develop gastrointestinal complications. The increased risk should be assessed according to individual risk factors, e.g. high age (>65 years), history of gastric or duodenal ulcer or upper gastrointestinal bleeding.

Combination therapy
In the case of combination therapy, the summaries of product characteristics of the respective medicines should be observed.

Co-administration with human immunodeficiency virus (HIV) protease inhibitors
Co-administration of PEPLOC OTC is not recommended with HIV protease inhibitors for which absorption is dependent on acidic intragastric pH such as atazanavir, due to significant reduction in their bioavailability (see section 4.5).

Long-term treatment
In long-term treatment, especially when exceeding a treatment period of 1 year, patients should be kept under regular surveillance.

Subacute cutaneous lupus erythematosus (SCLE)
Proton pump inhibitors are associated with very infrequent cases of subacute cutaneous lupus erythematosus (SCLE). If lesions occur, especially in sun exposed areas of the skin, and if accompanied by arthralgia, the patient should seek medical help promptly and the healthcare provider should consider stopping PEPLOC OTC. SCLE after previous treatment with a proton pump inhibitor may increase the risk of SCLE with other proton pump inhibitors.

Interference with laboratory tests
Increased chromogranin A (CgA) level may interfere with investigations for neuroendocrine tumours. To avoid this interference, PEPLOC OTC treatment should be stopped for at least 5 days before CgA measurements. If CgA and gastrin levels have not returned to reference range after initial measurement, measurements should be repeated 14 days after cessation of proton pump inhibitor treatment.

Acute interstitial nephritis
Acute interstitial nephritis has been observed in patients taking proton pump inhibitors (PPIs) including PEPLOC OTC. Acute interstitial nephritis may occur at any point during PPI therapy and is generally attributed to an idiopathic hypersensitivity reaction and is associated with damage to the tubulointerstitium, leading to acute kidney injury. Patients may present with varying signs and symptoms from symptomatic hypersensitivity reactions to non-specific symptoms of decreased renal function (e.g. malaise, nausea, anorexia). In reported case series, some patients were diagnosed on biopsy and in the absence of extra-renal manifestations (e.g. fever, rash or arthralgia). Interstitial nephritis may lead to renal failure. Discontinue PEPLOC OTC if acute interstitial nephritis develops (see section 4.8).

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'.

4.5 Interaction with other medicines and other forms of interaction
Concomitant intake of food has no influence on the bioavailability.

Coumarin anticoagulants (phenprocoumon or warfarin)
The response to anticoagulants such as warfarin, phenprocoumon and acenocoumarol may be affected by any concomitant medicine. There have been reports of increased INR and prothrombin time in patients receiving PPIs and warfarin or phenprocoumon concomitantly. Increases in INR and prothrombin time may lead to abnormal bleeding, and even death. It is therefore good practice to monitor the patient with additional PT (prothrombin time)/INR (international normalised ratio) determinations when PEPLOC OTC is initiated, discontinued or taken irregularly.

Medicines with pH-dependent absorption pharmacokinetics
PEPLOC OTC may reduce or increase the absorption of medicines whose bioavailability is pH-dependent, e.g. ketoconazole, itraconazole, posaconazole and other medicines like erlotinib.

HIV protease inhibitors
It has been shown that co-administration of atazanavir 300 mg/ritonavir 100 mg with proton pump inhibitors (PPIs) such as PEPLOC OTC resulted in a substantial reduction in the bioavailability of atazanavir. The absorption of atazanavir is pH-dependent. Therefore, PPIs, including PEPLOC OTC, should not be co-administered with atazanavir (see section 4.3).
If the combination of HIV protease inhibitors with a proton pump inhibitor is judged unavoidable, close clinical monitoring (e.g. virus load) is recommended. A PEPLOC OTC dose of 20 mg per day should not be exceeded. Dosage of the HIV protease inhibitor may need to be adjusted.

Methotrexate
Concomitant use of PPIs, including PEPLOC OTC, with methotrexate (primarily at high dose) may elevate and prolong serum levels of methotrexate and/or its metabolite hydroxymethotrexate, possibly leading to methotrexate toxicities. Therefore, in settings where high-dose methotrexate is used, for example cancer and psoriasis, a temporary withdrawal of PEPLOC OTC may need to be considered.
Inhibitors of CYP2C19
Inhibitors of CYP2C19, such as fluvoxamine, could increase the systemic exposure of pantoprazole. A dose reduction may be considered for patients treated long-term with high doses of PEPLOC OTC, or those with hepatic impairment.

Enzyme inducers affecting CYP2C19 and CYP3A4
Enzyme inducers affecting CYP2C19 and CYP3A4, such as rifampicin and St John's wort (*Hypericum perforatum*), may reduce the plasma concentrations of PPIs that are metabolized through these enzyme systems.

Other interactions studies:
The active ingredient of PEPLOC OTC is metabolised in the liver via the cytochrome P450 enzyme system. An interaction of PEPLOC OTC with other medicines or compounds which are metabolised using the same enzyme system cannot be excluded.
However no clinically significant interactions were observed when used concomitantly with caffeine, carbamazepine, diazepam, diclofenac, digoxin, ethanol, glibenclamide, metoprolol, naproxen, nifedipine, phenytoin, piroxicam, theophylline, warfarin and oral contraceptives.

There were no interactions with concomitantly administered antacids.

Interaction studies have also been performed by concomitantly administering pantoprazole with the respective antibiotics (clarithromycin, metronidazole, amoxicillin). No clinically relevant interactions were found.

4.6 Fertility, pregnancy and lactation
Safety in pregnancy and during lactation has not been established.

Pregnancy
Animal studies have shown reproductive toxicity. As a precautionary measure, it is preferable to avoid the use of PEPLOC OTC during pregnancy.

Breastfeeding
There is insufficient information on the excretion of pantoprazole in human milk but excretion into human milk has been reported. A risk to the new-borns/infants cannot be excluded. Therefore, breastfeeding while on PEPLOC OTC is not recommended.

Fertility
There was no evidence of impaired fertility following the administration of pantoprazole in animal studies. There is no data on fertility in humans with PEPLOC OTC.

4.7 Effects on ability to drive and use machines
PEPLOC OTC has no or negligible influence on the ability to drive and use machines.
PEPLOC OTC may affect driving ability due to potential adverse effects such as dizziness and visual disturbances (see section 4.8). If affected, patients should not drive or operate machines.

4.8 Undesirable effects
a. Summary of the safety profile
The most commonly reported side effects are diarrhoea and headache.
Approximately 5 % of patients can be expected to experience adverse drug reactions (ADRs).

b. Tabulated list of adverse reactions

System organ class	Frequency	Side effects
Infections and Infestations	*Frequency unknown*	*Clostridium difficile*-associated diarrhoea*
Blood and lymphatic system disorders	*Less frequent*	Leukopaenia, thrombocytopaenia, pancytopaenia, agranulocytosis
Immune system disorders	*Less frequent*	Anaphylactic reactions including anaphylactic shock and angioedema
Metabolism and nutrition disorders	*Less frequent*	Increased bilirubin, elevated triglycerides and increased body temperature, lipid increases, hypocalcaemia**, hyperlipidaemia, weight changes
Psychiatric disorders	*Less frequent*	Mental depression, sleep disorders, depression, disorientation
	Frequency unknown	Hallucination*, confusion*
Nervous system disorders	*Frequent*	Headache
	Less frequent	Dizziness, taste disorders
	Frequency unknown	Paraesthesia
Eye disorders	*Less frequent*	Disturbances in vision (blurred vision)
Gastrointestinal disorders	*Frequent*	Gastrointestinal complaints such as upper abdominal pain, diarrhoea, constipation or flatulence
	Less frequent	Nausea, vomiting, dry mouth, abdominal distension and bloating, abdominal pain and discomfort
	Frequency unknown	Microscopic colitis*
Hepatobiliary disorders	*Less frequent*	Increased bilirubin
	Frequency unknown	Severe hepatocellular damage* leading to jaundice* with or without hepatic failure* and increased liver enzymes (transaminases, γ-GT)
Skin and subcutaneous tissue disorders	*Less frequent*	Allergic reactions such as pruritus and skin rash, urticaria
	Frequency unknown	Severe skin reactions such as Stevens-Johnson syndrome*, erythema multiforme*, toxic epidermal necrolysis* (Lyell syndrome) and photosensitivity*, drug reaction with eosinophilia and systemic symptoms (DRESS)*, subacute cutaneous lupus erythematosus*
Musculoskeletal, connective tissue and bone disorders	*Less frequent*	Arthralgia, myalgia, fracture of the hip, wrist or spine
	Frequency unknown	Hyponatraemia, hypomagnesaemia, hypocalcaemia in association with hypomagnesaemia, muscle spasm as a consequence of electrolyte disturbance*
Renal and urinary disorders	*Frequency unknown*	Interstitial nephritis* (in some patients' renal failure has been reported concomitantly) (see section 4.4)
Reproductive system and breast disorders	*Less frequent*	Gynaecomastia
General disorders and administrative site conditions	*Less frequent*	Asthenia, fatigue, malaise, and peripheral oedema, body temperature increased

*Post-marketing reports.
**Hypocalcaemia in association with hypomagnesaemia.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website. An email can be sent directly to the company, pharmacovigilance@pharmadynamics.co.za, to ensure safety of the product.

4.9 Overdose
Signs and symptoms:
The described side effects may be exacerbated.
There are no known symptoms of overdose in man.
Systemic exposure with up to 240 mg administered intravenously over 2 minutes was well tolerated.

Management of overdose:
As pantoprazole is extensively protein bound, it is not readily dialysable.
No specific therapeutic recommendation can be made in cases of overdosage with clinical signs of intoxication.
Treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Proton pump inhibitors
ATC code: A02BC02
Pharmacological classification: A 11.4.3 Medicines acting on the gastrointestinal tract – Other.

Mechanism of action:
Pantoprazole is a proton pump inhibitor, i.e. it inhibits specifically and dose-proportionally H^+, K^+-ATPase (adenosine triphosphatase), the enzyme which is responsible for gastric acid secretion in the parietal cells of the stomach.

Pantoprazole is a substituted benzimidazole which accumulates in the acidic compartment of the parietal cells after absorption. In the parietal cell it is protonated and chemically rearranged to the active inhibitor, a cyclic sulphonamide, which binds to the H^+, K^+-ATPase, thus inhibiting the proton pump and causing suppression of stimulated and basal gastric acid secretion after single and multiple intravenous and oral pantoprazole dosing. Because pantoprazole acts distal to the receptor level, it can influence gastric acid secretion irrespective of the nature of the stimulus.

Pantoprazole exerts its full effect in a strongly acidic environment (pH < 3) and remains mostly inactive at higher pH values, which explains its selectivity for the acid secreting parietal cells of the stomach.

Therefore, the complete pharmacological and therapeutic effect for pantoprazole can only be achieved in the acid secreting parietal cells. By means of a feedback mechanism this effect is diminished at the same rate as acid secretion is inhibited.

Effect on gastric acid secretion
Although pantoprazole has a half-life of approximately 1 hour, the antisecretory effect increases during repeated once daily administration, demonstrating that the duration of action markedly exceeds the serum elimination half-life.

5.2 Pharmacokinetic properties
Absorption:
Pantoprazole is unstable in acid and is administered orally in the form of an enteric coated tablet. Absorption takes place in the small intestine. On average, the maximum serum/plasma concentrations are approximately 2 - 3 µg/mL about 2½ hours after administration of 40 mg pantoprazole daily, as a single or multiple doses in healthy volunteers. The absolute systemic bioavailability of pantoprazole from single and multiple oral doses of pantoprazole is approximately 77 %.
Concomitant intake of food had no influence on area under the plasma concentration-timed curve (AUC), maximum serum concentration and thus bioavailability. Only the variability of the lag-time will be increased by concomitant food intake.

Distribution:
Pantoprazole's serum protein binding is about 98 %. Volume of distribution is about 0.15 L/kg.

Biotransformation:
Pantoprazole is almost exclusively metabolised in the liver. The main metabolite is desmethylpantoprazole, which is conjugated with sulphate other metabolic pathway includes oxidation by CYP3A4.

Elimination:
Renal elimination represents the most important route of excretion (approximately 80 %) for the metabolites of pantoprazole. The balance is excreted with the faeces. The half-life of the main metabolite is approximately 1½ hours, which is slightly longer than that of pantoprazole.

Linearity/non-linearity:
The plasma kinetics for pantoprazole administration are linear over the dose range of 10 - 80 mg.

Pharmacokinetics in special patient groups
Pharmacokinetic profile in patients with impaired liver or renal function
For patients with mild to moderately severe hepatic cirrhosis, the elimination half-life values increase from 1 hour to between 7 - 9 hours. The AUC values increase by a factor of 6 - 8, while the maximum serum concentration only increases by a factor of 1,5 in comparison with healthy subjects.

In patients with renal impairment, the half-life of the main metabolite is moderately increased but there is no accumulation at therapeutic doses. The half-life of pantoprazole in patients with renal impairment is comparable to the half-life of pantoprazole in healthy subjects. Pantoprazole is poorly dialysed. A slight increase in AUC and Cmax occurs in elderly volunteers compared with younger people.

Poor metabolisers
Approximately 3 % of the European population lack a functional CYP2C19 enzyme and are called poor metabolisers. In these individuals the metabolism of pantoprazole is probably mainly catalysed by CYP3A4. After a single-dose administration of 40 mg pantoprazole, the mean area under the plasma concentration-time curve was approximately 6 times higher in poor metabolisers than in subjects having a functional CYP2C19 enzyme (extensive metabolisers). Mean peak plasma concentrations were increased by about 60 %. These findings have no implications for the posology of pantoprazole.

Elderly
A slight increase in AUC and C_{max} in elderly volunteers compared with younger counterparts is also not clinically relevant.

Paediatric population
Following administration of single oral doses of 20 or 40 mg pantoprazole to children aged 5 - 16 years AUC and C_{max} were in the range of corresponding values in adults.

Following administration of single intravenous (IV) doses of 0,8 or 1,6 mg/kg pantoprazole to children aged 2 - 16 years there was no significant association between pantoprazole clearance and age or weight. AUC and volume of distribution were in accordance with data from adults.

5.3 Preclinical safety data
Non-clinical data reveal no special hazard to humans based on conventional studies of safety pharmacology, repeated dose toxicity and genotoxicity.

A two-year carcinogenicity study in rats found both neuroendocrine neoplasms and squamous cell papillomas in the fore stomach of rats.

The mechanism leading to the formation of gastric carcinoids by substituted benzimidazoles has been carefully investigated and allows the conclusion that it is a secondary reaction to the massively elevated serum gastrin levels occurring in the rat during chronic high-dose treatment.

In the two-year rodent study, an increased number of liver tumours was observed in rats and in female mice and was interpreted as being due to pantoprazole's high metabolic rate in the liver.

A slight increase of neoplastic changes of the thyroid was observed in the group of rats receiving the highest dose (200 mg/kg). The occurrence of these neoplasms is associated with the pantoprazole-induced changes in the breakdown of thyroxine in the rat liver. As the therapeutic dose in man is low, no harmful effects on the thyroid glands are expected.

In a peri-postnatal rat reproduction study designed to assess bone development, signs of offspring toxicity (mortality, lower mean body weight, lower mean body weight gain and reduced bone growth) were observed at exposures (C_{max}) approximately 2x the human clinical exposure. By the end of the recovery phase, bone parameters were similar across groups, and body weights were also trending toward reversibility after a medicine-free recovery period. The increased mortality has only been reported in pre-weaning rat pups (up to 21 days age), which is estimated to correspond to infants up to the age of 2 years old. The relevance of this finding to the paediatric population is unclear. A previous peri-postnatal study in rats at slightly lower doses found no adverse effects at 3 mg/kg compared with a low dose of 5 mg/kg in this study.

Investigations revealed no evidence of impaired fertility or teratogenic effects.

Penetration of the placenta was investigated in the rat and was found to increase with advanced gestation. As a result, concentration of pantoprazole in the foetus is increased shortly before birth.

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Tablet core:
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
Triethyl citrate
Yellow iron oxide.

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
30 months.

6.4 Special precautions for storage
Store at or below 25 ºC. Protect from moisture.
Store blister in the outer carton until required for use.

6.5 Nature and contents of container
PEPLOC OTC tablets are packed in aluminium-polyamide-PVC/aluminium blister strips.
7 or 14 tablets are packed in an outer carton.

6.6 Special precautions for disposal
No special requirements.

7. HOLDER OF THE CERTIFICATE OF REGISTRATION
Pharma Dynamics (Pty) Ltd
1st Floor Grapevine House, Steenberg Office Park
Silverwood Close
Westlake, 7945
Cape Town, South Africa
Tel: +27 21 707 7000
or 0860-PHARMA (742 762)

8. REGISTRATION NUMBER
A43/11.4.3/0344

9. DATE OF FIRST AUTHORISATION
Date of registration: 26 November 2015

10. DATE OF REVISION OF THE TEXT
17 January 2025

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pharma dynamics

PATIENT INFORMATION LEAFLET

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

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 B12
- use of PEPLOC OTC taken to prevent gastroduodenal ulcers, induced by nonselective nonsteroidal 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, pharmacist or nurse. 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 pantoprazole 20 mg.

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, triethyl citrate, yellow iron oxide.

What PEPLOC OTC looks like and contents of the pack
PEPLOC OTC: Orangish, biconvex and oval gastro-resistant tablets.

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
Pharma Dynamics (Pty) Ltd
1st Floor Grapevine House, Steenberg Office Park
Silverwood Close
Westlake, 7945
Cape Town, South Africa
Tel: + 27 21 707 7000
or 0860-PHARMA (742 762)

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pharma dynamics

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS: S2

PEPLOC OTC 20 mg tablette
Pantoprasool
PEPLOC OTC bevat suiker (mannitol 70,50 mg/tablet)
Wesenlik 'natriumvry'.

Lees hierdie hele inligtingsblad deeglik deur, aangesien dit belangrike inligting vir u bevat.
PEPLOC OTC is beskikbaar vir u sonder 'n dokter se voorskrif, om 'n minder ernstige siekte te behandel. U moet nietemin steeds PEPLOC OTC omsigtig gebruik, om die beste resultate daarvan te verkry.

- Hou hierdie inligtingsblad. Dit mag nodig wees vir u om dit weer te lees.
- Moet nie PEPLOC OTC met enige ander persoon deel nie.
- Vra u gesondheidsorgverskaffer of apteker, indien u meer inligting of advies benodig.
- U moet 'n dokter besoek, indien u simptome vererger, of nie verbeter na 14 dae nie.

Inhoud van hierdie inligtingsblad
1. Wat PEPLOC OTC is en waarvoor dit gebruik word
2. Wat u nodig het om te weet, voordat u PEPLOC OTC neem
3. Hoe om PEPLOC OTC te neem
4. Moontlike newe-effekte
5. Hoe om PEPLOC OTC te bewaar
6. Verpakkingsinhoud en ander inligting

1. Wat PEPLOC OTC is en waarvoor dit gebruik word
PEPLOC OTC bevat pantoprasool, een van 'n groep medisyne wat protonpomp remmers genoem word en gebruik word om sekere toestande, waar daar té veel suur in die maag teenwoordig is, te behandel.

PEPLOC OTC word aangedui vir
- die tydelike, korttermyn verligting van sooibrand en hiperasiditeit teen 'n maksimum daaglikse dosis van 20 mg en 'n maksimum behandelingstydperk van 14 dae.

2. Wat u nodig het om te weet, voordat u PEPLOC OTC neem
Moet nie PEPLOC OTC neem:
- indien u hipersensitief (allergies) is vir pantoprasool of enige van die ander bestanddele van PEPLOC OTC nie (sien afdeling 6)
- indien u lewerfunksie belemmer is nie
- PEPLOC OTC moet nie vir kinders gegee word nie
- indien u atasanavir neem nie ('n medisyne wat gebruik word vir die behandeling van menslike immuniteitsgebreksvirus (MIV)).

Waarskuwings en voorsorgmaatreëls
Neem spesiale sorg met PEPLOC OTC:
- indien u belemmerde nierfunksie het
- indien u warfarien neem (medisyne wat die risiko vir bloedklonte verlaag)
- indien u lewersiekte het
- indien u lae magnesiumvlakke in u bloed het
- indien u tans behandel word, of 'n geskiedenis van enige maligniteite (kanker of gewas) in die maagomgewing het, of vermoed dat u tekens van maagkanker toon nie (simptome sluit gewigsverlies, donker stoelgang, aptytverlies, gevoel van versadiging, of 'n sensasie van 'n knop in u maag, in)
- indien u 'n geskiedenis van vitamien B12 tekort het en langtermyn behandeling (bv. langer as 3 jaar) met PEOPLOC OTC ontvang. PEPLOC OTC, soos met alle suur-verlagende middels, mag lei tot 'n verlaagde absorbsie van vitamien B12
- die gebruik van PEPLOC OTC om gastroduodenale ulkusse te voorkom, wat deur nie-selektiewe niesteroïdale anti-inflammatoriese middels (NSAIM) aangewakker word, moet nie deur pasiënte wie voortdurende NSAIM behandeling benodig en 'n verhoogde risiko om gastro-intestinale komplikasies te ontwikkel, geneem word nie
- indien u diarree ontwikkel wat nie verbeter nie, kontak u dokter of gesondheidsorgdeskundige so gou as moontlik, aangesien PEPLOC OTC geassosieer word met 'n geringe toename in infektiewe diarree
- indien u ouer as 50 jaar is, of indien u PEPLOC OTC langdurig of teen hoë dosisse neem, mag dit lae magnesiumvlakke in die liggaam veroorsaak en die risiko vir beenfrakture in die heup, gewrig of ruggraat, verhoog
- indien u 'n beenfraktuur in die heup, gewrig of ruggraat, as gevolg van lae magnesium het of gehad het
- indien u MIV protease-remmers soos atasanavir (vir die behandeling van MIV infeksie), op dieselfde tydstip as pantoprasool neem, vra u dokter vir spesifieke advies
- indien u 'n veluitslag ontwikkel, veral op gedeeltes wat aan die son blootgestel is, mag dit nodig wees om u behandeling met PEPLOC OTC te staak. Onthou om ook enige ander newe-effekte, soos pyn in u gewrigte te noem
- indien u PEPLOC OTC op 'n langtermyn basis (langer as 1 jaar) neem, sal u dokter u waarskynlik onder gereelde waarneming plaas. U moet enige nuwe en uitsonderlike simptome en omstandighede aanmeld, wanneer u die dokter besoek
- indien u pantoprasool, soos bevat in PEPLOC OTC, vir meer as drie maande neem, is dit moontlik dat die magnesiumvlakke in u bloed mag daal. Lae magnesiumvlakke het uitputting, onwillekeurige spiersametrekkings, disoriëntasie, konvulsies, duiseligheid, of verhoogde hartklop tot gevolg. Indien u enige van hierdie simptome ervaar, vertel u dokter onmiddellik. Lae magnesiumvlakke mag ook lei tot 'n afname in kalium- of kalsiumvlakke in die bloed. U dokter mag besluit om gereelde bloedtoetse uit te voer, om u magnesiumvlakke te monitor
- indien daar 'n vermindering in u urienvolume is, of daar bloed in u urine opgemerk word
- indien u binnekort 'n spesifieke bloedtoets (chromogranien A) sal ondergaan, moet PEPLOC OTC behandeling vir ten minste 5 dae gestaak word, voordat chromogranien A (CgA) bepalings geneem word en 'n verdere toets mag benodig word 14 dae nadat behandeling

Ander medisyne en PEPLOC OTC
Vertel altyd u gesondheidsorgverskaffer indien u enige ander medisyne neem (Dit sluit aanvullende of tradisionele medisyne in).
- medisyne wat u bloed verdun, soos warfarien. PEPLOC OTC mag die effek van hierdie medisyne verander en u gesondheidsorgverskaffer sal dus wil monitor, of u bloed goed genoeg stol
- sekere medisyne wat gebruik word om swaminfeksies te behandel, soos ketokonasool. PELOC OTC mag die absorpsie daarvan verlaag
- atasanavir, 'n verbinding wat in anti-MIV medisyne voorkom. PEPLOC OTC mag die bloedvlakke van hierdie medikasie, verlaag. U moet nie PEPLOC OTC gelyktydig saam met atasanavir neem nie (sien Moet nie PEPLOC OTC neem)
- metotreksaat (hoë dosisse wat gebruik word vir die behandeling van sekere kankers). PEPLOC OTC mag die bloedvlakke van hierdie medisyne verhoog en moontlik lei tot metotreksaat toksisiteit
- fluvoksamien (gebruik om depressie en ander psigiatriese siektes te behandel). Indien u fluvoksamien neem, mag u dokter die dosis verlaag
- Johanneskruid (*Hypericum perforatum*) (gebruik om ligte depressie te behandel)
- die aktiewe bestanddeel pantoprasool, word gemetaboliseer deur seker lewerensieme, wat 'n wisselwerking mag toon met ander medisyne of verbindings, wat ook deur hierdie ensieme gemetaboliseer word.

PEPLOC OTC saam met kos en drinkgoed
PEPLOC OTC 20 mg tablette daagliks, moet voor 'n maaltyd, verkieslik in die oggend geneem word.

Swangerskap, borsvoeding en fertiliteit
U moet PEPLOC OTC nie neem indien u swanger is of u baba borsvoed nie.
Indien u swanger is, of u baba borsvoed, vermoed dat u swanger mag wees, of 'n baba beplan, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies, voordat u PEPLOC OTC neem. Veiligheid tydens swangerskap en borsvoeding is nie vasgestel nie.

Daar is geen data beskikbaar, aangaande fertiliteit by mense wie PEPLOC OTC gebruik nie.

Bestuur en die hantering van masjiene
PEPLOC OTC mag wasige visie of duiseligheid veroorsaak, wat u vermoë om te bestuur, of masjinerie te hanteer, aantas. Dit is nie altyd moontlik om te voorspel tot watter mate PEPLOC OTC met die daaglikse aktiwiteite van 'n pasiënt sal inmeng nie. Pasiënte moet verseker dat hulle nie by bogenoemde aktiwiteite betrokke raak, totdat hulle bewus is to watter mate PEPLOC OTC hulle aantas nie.

PEPLOC OTC bevat natrium
PEPLOC OTC bevat natrium. PEPLOC OTC bevat minder as 1 mmol (0,023 g) natrium per tablet, dit wil sê wesenlik 'natriumvry'.

3. Hoe om PEPLOC OTC te neem
Moet nie medisyne wat vir u voorgeskryf is, met enige ander persoon deel nie.
Neem PEPLOC OTC altyd presies soos in hierdie in inligtingsblad aangewys word, of soos deur u dokter, apteker, of verpleegkundige aanbeveel word. Raadpleeg u dokter, apteker of verpleegkundige, indien u onseker is.

Die tablette moet heel gesluk word, met water.
Moet nie die tablet verkrummel, breek of kou nie.

Dit mag verskeie dae neem voordat PEPLOC OTC begin om u simptome te verlig.
Om te help om u simptome te verlig, mag teensuurmiddels saam met PEPLOC OTC geneem word, tensy u dokter u aangeraai het om dit nie te gebruik nie.

Volwassenes:
Die gewone dosis is een 20 mg tablet een keer daagliks, vir 'n maksimum tydperk van 14 dae.

Kinders:
Veiligheid en doeltreffendheid vir kinders, is nog nie vasgestel nie.

Indien u meer PEPLOC OTC neem as wat u behoort
In die geval van 'n oordosering, raadpleeg u dokter of apteker. Indien beide nie beskikbaar is nie, kontak u naaste hospitaal of gifbeheersentrum.

Neem hierdie inligtingsblad en enige oorblywende tablette saam met u, sodat u dokter weet wat u geneem het.

Indien u vergeet om 'n dosis PEPLOC OTC te neem
Indien u 'n dosis oorgeslaan het, neem dit so gou as wat u onthou. Indien dit amper tyd is vir die volgende dosis, slaan die vergete dosis oor en hou aan om die tablet op die gewone tyd te neem. Moenie 'n dubbeldosis neem om op te maak vir die vergete individuele dosisse nie.

4. Moontlike newe-effekte
PEPLOC OTC kan newe-effekte hê.
Nie alle newe-effekte wat aangemeld is vir PEPLOC OTC word in hierdie inligtingsblad ingesluit nie. Sou u algemene gesondheid versleg, of indien u enige ongunstige effek ervaar, terwyl u PEPLOC OTC neem, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, staak die gebruik van PEPLOC OTC en vertel u dokter onmiddellik, of gaan na die ongevalle-afdeling by u naaste hospitaal:
- swelling van die hande, voete, enkels, gesig, lippe, mond, tong of keel, wat die slukproses of asemhaling mag bemoeilik.
- uitslag of gejeuk.

Hierdie is alles baie ernstige newe-effekte. Indien u dit ondervind, kon u 'n ernstige allergiese reaksie teenoor PEPLOC OTC ervaar het. U mag dringende mediese aandag of hospitalisasie benodig.

Vertel u dokter onmiddellik of gaan na die ongevalle-afdeling by u naaste hospitaal indien u enige van die volgende opmerk:
- maagpyn (erg)
- koors, uitslag en vergrote niere, somtyds gepaardgaande met pynlike urinering en laer rugpyn (ernstige inflammasie van die niere), wat moontlik mag lei tot nierversaking
- blaasvorming, losmaking, afskilfering of rooiheid van die vel, Stevens-Johnson-sindroom, erythema multiforme (begin met griep-soortige simptome, gevolg deur 'n pynlike, rooi of perserige uitslag wat versprei en blase vorm), geneesmiddel uitslag met eosinofilie en sistemiese simptome (GRESS), wat 'n tipe geneesmiddel allergie is en voorkom as 'n reaksie met 'n groot verskeidenheid medikasies
- geel velkleur en/of geel oë, swart, teer-agtige stoelgang (simptome van lewersiekte)
- wasige sig.

Hierdie is alles ernstige newe-effekte. U mag dringende mediese aandag benodig.

Vertel u dokter indien u enige van die volgende opmerk:
Algemene newe-effekte:
- diarree of hardlywigheid, buikpyn, winderigheid
- hoofpyn.

Minder algemene newe-effekte:
- lae hoeveelhede wit selle in u bloed
- hoë konsentrasie vetagtige produkte in u bloed, toename in liggaamstemperatuur
- slaapprobleme, depressie, disoriëntasie
- duiseligheid, smaaksteurnis, of algehele afwesigheid van smaaksensasie
- naarheid en/of braking, droë mond, voel opgeblase, maagpyn en ongemak
- ander velaandoenings
- pyn in die gewrigte of spiere, frakture van die heup, gewrig, of ruggraat
- swelling en vergroting van borste by mans
- gevoel van swakheid, uitputting, malaise (voel sleg), swelling van die hande en voete
- spierrigiditeit of styfheid.

Die volgende newe-effekte is aangemeld, maar die frekwensie van voorkoms, is onbekend:
- inflammasie in die dikderm, wat voortdurende waterige diarree veroorsaak
- lae sout-, magnesium-, of kalsiumvlakke in die bloed
- hallusinasie, verwarring
- gevoel van tinteling, prikkeling, spelde en naalde, brandende sensasie, of gevoelloosheid
- spierspasma as gevolg van 'n elektrolietversteuring
- 'n tipe nierprobleem (akute interstisiële nefritis). Sommige mense wie protonpomp remmer (PPR) medisyne neem, insluitend PEPLOC OTC, mag 'n nierprobleem, wat akute interstisiële nefritis genoem word, ontwikkel. Dit kan op enige tydstip tydens die behandeling met PPR medisyne voorkom. Kontak u dokter dadelik, indien u minder urineer as gewoonlik, of bloed in u urine opmerk.

Indien u enige newe-effekte opmerk, wat nie in hierdie inligtingsblad genoem word nie, lig asseblief u dokter of apteker in.

Aanmelding van newe-effekte
Indien u newe-effekte ervaar, praat met u dokter, apteker of verpleegkundige. U kan ook newe-effekte aanmeld by SAHPRA via die Med Safety toepassing (Medsafety X SAHPRA) en eReporting platform (who-umc.org), wat op SAHPRA se webtuiste gevind kan word. Deur die aanmelding van newe-effekte, kan u help om meer inligting aangaande die veiligheid van PEPLOC OTC in te win. U kan ook 'n epos direk aan die maatskappy stuur, pharmacovigilance@pharmadynamics.co.za, om die veiligheid van die produk te verseker.

5. Hoe om PEPLOC OTC te bewaar
Bewaar alle medisyne buite die bereik van kinders.
Bewaar teen of benede 25 °C.
Beskerm teen vog.
Bewaar stulpstrook in die buitenste kartonhouer totdat dit benodig word vir gebruik.
Moet nie die tablette na die vervaldatum wat op die karton of stulpstrook gedruk is, gebruik nie.
Neem alle ongebruikte medisyne na u apteker terug.
Moet nie ongebruikte medisyne in afvoerpype en rioolstelsels (bv. toilette), weggooi nie.

6. Verpakkingsinhoud en ander inligting
Wat PEPLOC OTC bevat:
Die aktiewe bestanddeel is pantoprasool.
Elke tablet bevat natriumpantoprasoolseskihidraat gelykstaande aan pantoprasool 20 mg.

Die ander bestanddele is
Tabletkerne:
Magnesiumstearaat, mannitol, natriumkarmellose, natriumstyselglikolaat tipe A, watervrye kolloïdale silika, watervrye natriumkarbonaat

Tabletbedekking:
Geel ysteroksied, hipromellose, metakrielsuur – etielakrilaatkopolimeer, propileenglikool, titaandioksied, triëtielsitraat.

Hoe PEPLOC OTC lyk en die verpakkingsinhoud
Oranjerige, bikonveks en ovaal, maagweerstandige tablette.

PEPLOC OTC tablette word verpak in aluminium-poliamied PVC/aluminium stulpstroke. 7 of 14 tablette word verpak in 'n buitenste kartonhouer.

Eienaar van die Registrasiesertifikaat
Pharma Dynamics (Edms.) Bpk.
1ste Vloer Grapevine House, Steenberg Office Park
Silverwood Close
Westlake, 7945
Kaapstad, Suid-Afrika
Tel: +27 21 707 7000
of 0860-PHARMA (742 762)

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