

PRODUCT MONOGRAPH

OD-PEP-D CAPSULES

Each hard gelatin capsule of OD-PEP-D contains three smartlets:

Each yellow enteric-coated smartlet contains:

Pantoprazole Sodium Sesquihydrate equivalent to Pantoprazole 40mg

Each white film coated smartlet contains:

Domperidone 10 mg IR

Each red delayed-release smartlet contains:

Domperidone 10 mg SR

Hard Gelatin Capsule

Gerd – Agents to treat Acid peptic Disorders

Manufactured By:

Panacea Biotec Limited.

(Address as on Package)

Date of Preparation:

(24/07/2019)

PART I: HEALTH PROFESSIONAL INFORMATION	Page No.
SUMMARY PRODUCT INFORMATION	3
INDICATIONS AND CLINICAL USE	4
CONTRAINDICATIONS	6
WARNINGS AND PRECAUTIONS	6
ADVERSE REACTIONS	6
DRUG INTERACTIONS	7
DOSAGE AND ADMINISTRATION	8
OVERDOSAGE	9
ACTION AND CLINICAL PHARMACOLOGY	9
STORAGE AND STABILITY	12
SPECIAL HANDLING INSTRUCTIONS	12
DOSAGE FORMS, COMPOSITION AND PACKAGING	12
PART II: SCIENTIFIC INFORMATION	
PHARMACEUTICAL INFORMATION	13
CLINICAL TRIALS	15
REFERENCES	18
PART III: PATIENT INFORMATION	19

OD-PEP-D

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Pantoprazole Sodium Sesquihydrate equivalent to Pantoprazole 40mg

Domperidone 10mg IR

Domperidone 10mg SR

Hard Gelatin Capsule

GERD – Agents to treat Acid peptic Disorders

PART I: HEALTH PROFESSIONAL INFORMATION

SUMMARY PRODUCT INFORMATION

Route of Administration	Dosage Form / Strength	Approved Indications
Oral	Hard Gelatin Capsule Pantoprazole Sodium Sesquihydrate equivalent to Pantoprazole 40mg Domperidone 10mg IR Domperidone 10mg SR	OD-PEP-D is an acid peptic disorder drug indicated for: - GERD

INDICATIONS AND CLINICAL USE:

OD-PEP-D which is in **hard gelatin capsule** form is indicated in the management of **gastroesophageal reflux disease**; gastritis, non-ulcer dyspepsia, gastric or duodenal ulcer, dyspepsia, bloating, fullness, belching, NSAID-induced dyspepsia.

Clinical Use in special population:

Pantoprazole :

Hepatic impairment:

There is a slight increase (1.5 fold) in maximum drug concentrations in patients with mild to severe hepatic impairment. No dosage adjustment is needed in patients with mild to severe hepatic impairment.

Renal impairment:

Pharmacokinetic parameters for Pantoprazole in patients with severe renal impairment are similar to those of healthy subjects. No dosage adjustment is needed in patients with renal impairment.

Gender:

No dosage adjustment is needed based on gender.

Pediatrics:

The pharmacokinetics of Pantoprazole have not been investigated in patients <18 years of age.

Geriatrics:

No dosage adjustment is recommended based on age.

Domperidone :

Hepatic impairment:

There is no published pharmacokinetic data in patients with hepatic impairment. Because Domperidone is extensively metabolized, response to the drug should be carefully monitored in this patient population.

Neonates:

Domperidone is not recommended for use in neonates.

Breast milk:

Domperidone may precipitate galactorrhea and improve postnatal lactation. It is secreted in breast milk in very small quantities and thus insufficient to be considered harmful.

Pediatrics: Domperidone is not recommended other than for treatment of nausea and vomiting in patients undergoing cancer therapy. There may be an increased risk for extrapyramidal reactions in young children because of an incompletely developed blood brain barrier.

Pregnant women: The safety of Domperidone has not been proven, therefore its use is not recommended in pregnant women.

Geriatrics: No special precautions are necessary in older patients.

OD-PEP-D should be used with caution in conditions where the individual drugs have been used with precautionary approach.

CONTRAINDICATIONS:

OD-PEP-D is contraindicated in patients with known hypersensitivity to Pantoprazole or Domperidone.

Pregnancy and Lactation

Due to lack of controlled studies in pregnant and lactating women, use of OD-PEP-D is contraindicated in this group of patients

WARNING AND PRECAUTIONS:

OD-PEP-D shall be given with care to patients with renal dysfunction or hepatic dysfunction

ADVERSE EFFECTS :

Pantoprazole

the adverse reactions associated with Pantoprazole include Headache, Diarrhoea, Skin rash, Pruritus and Dizziness.

Domperidone

Serum prolactin level may rise resulting in galactorrhea in females and less frequently gynaecomastia in males due to Domperidone. Dry mouth, Thirst, Headache, Nervousness, Drowsiness, Diarrhoea, Skin rashes and Itching may follow treatment with Domperidone.

DRUG INTERACTIONS :

Pantoprazole

Pantoprazole is metabolized through the cytochrome P450 system, primarily the CYP2C19 and CYP3A4 isoenzymes, and subsequently undergoes phase II conjugation. Based on studies evaluating possible interactions of Pantoprazole with other drugs metabolized by the cytochrome P450 system, no dosage adjustment is needed with concomitant use of the following drugs: theophylline, cisapride, antipyrine, caffeine, carbamazepine, diazepam, diclofenac, digoxin, ethanol, glyburide, oral contraceptives (levonorgestrel / ethinylestradiol), metoprolol, nifedipine, phenytoin or warfarin. Clinically relevant interactions of Pantoprazole with other drugs with the same metabolic pathways are not expected. Therefore, when co-administered with Pantoprazole, adjustment of the dosage of Pantoprazole with such drugs may not be necessary. There was also no interaction with concomitantly administered antacids.

Because of profound and long lasting inhibition of gastric acid secretion, it is theoretically possible that Pantoprazole may interfere with absorption of drugs where gastric pH is an important determinant of their bioavailability (e.g. Ketoconazole, Ampicillin esters, and iron salts).

Domperidone

Anti-cholinergic drugs may inhibit the anti-dyspeptic effects of Domperidone. Antimuscarinic agents and opioid analgesics may antagonise the effect of Domperidone. Domperidone suppresses the peripheral effects (digestive disorders, nausea and vomiting) of dopaminergic agonists. Since Domperidone has gastrokinetic effects, it could influence the absorption of concomitant orally administered drugs, particularly those with sustained release or enteric coated formulations.

As Domperidone interferes with serum prolactin levels, it may interfere with other hypoprolactinaemic agents and with some diagnostic tests.

Antacids and anti-secretory agents lower the oral bioavailability of Domperidone. They should be taken after meals and not before meals, i.e. they should not be

taken simultaneously with Domperidone. Reduced gastric acidity impairs the absorption of Domperidone.

Oral bioavailability is decreased by prior administration of Cimetidine or Sodium Carbonate

DOSAGE AND ADMINISTRATION :

Dosage Schedule of Each Ingredient vis-à-vis Dosage Schedule of the FDC

Dosage schedule of the FDC

a) **Composition** of the FDC – Each OD-PEP-D capsule contains

Pantoprazole Sodium Sesquihydrate equivalent to Pantoprazole 40mg

Domperidone 10mg IR

Domperidone 10mg SR

b) **Dosage Form** – Hard Gelatin Capsule

Administration: - The usual recommended dose of OD-PEP-D is one capsule daily before breakfast. Swallow capsule as a whole, do not chew the capsule

OVERDOSE :

In the event of overdosage, gastric lavage should be performed. Symptomatic and supportive measures are recommended.

ACTION AND CLINICAL PHARMACOLOGY :

PHARMACOKINETICS

Pantoprazole

Pantoprazole is rapidly absorbed after oral administration, with peak plasma concentrations (C_{max}) of 1.1 to 3.1. (mean 2.1) mg/L occurring within 2 to 4 (mean 2.7) hours (t_{max}) after ingestion of an enteric coated 40 mg tablet. The volume of distribution is low (mean 0.16 L/kg at steady state) due to high degree of plasma protein binding (~98%). Plasma Pantoprazole concentrations decline monophasically after oral administration, with a mean plasma terminal half-life (t_{1/2β}) of 0.9 to 1.9 hours. However, since inhibition of acid secretion is non-competitive or irreversible, there is no correlation between plasma levels and the duration of action of Pantoprazole. Concomitant intake of food has no influence on the bioavailability of Pantoprazole, and any possible retardant effect of food on the rate of drug absorption is not of clinical relevance, considering the prolonged antisecretory action of Pantoprazole. The enteric coating does not influence the bioavailability of Pantoprazole.² Pantoprazole undergoes extensive hepatic metabolism via cytochrome P450 oxidase followed by sulphate conjugation. Elimination of Pantoprazole is predominantly renal, with ~80% of an oral dose being excreted as urinary metabolite; the remainder is excreted in the faeces and originates primary from biliary secretion.

Domperidone

Domperidone is rapidly and almost completely (93%) absorbed after oral administration. Peak plasma concentrations occur within 30 min. after oral administration. The peak plasma concentration value after a 20mg oral dose is in

the range of 15 to 19 ng/ml. The mean elimination half life ranges from 12 - 16 hours for an oral dose. Oral bioavailability of Domperidone is 13 - 17% because of extensive presystemic metabolism in gut wall and liver.

Administration of Domperidone 90 minutes after a meal increases bioavailability whereas Cimetidine or alkali pretreatment reduces bioavailability. Domperidone is strongly bound to plasma proteins (90-93%). Domperidone undergoes extensive biotransformation with <1% excreted unchanged in urine.

Pharmacodynamic :

Pantoprazole :

Pantoprazole, a benzimidazole sulphoxide derived prodrug, is an irreversible proton pump inhibitor. Pantoprazole, being a weak base, is highly ionized at low pH and readily accumulated in the highly acidic canalicular lumen of the stimulated parietal cell in the stomach. In this acidic environment, it is protonated and rapidly converted to a cationic cyclic sulphonamide.

The sulphonamide binds covalently to cysteine residues on the luminal (acidic) surface of H^+ / K^+ -ATPase to form a mixed disulphide; thus causing irreversible inhibition of the gastric proton pump. This inhibition of the gastric proton pump or H^+ / K^+ - ATPase (which represents the final step in the secretory process), suppresses gastric acid secretion.

Domperidone :

Domperidone, a benzimidazole derivative (structurally related to the butyrophenones), acts by selectively antagonizing the peripheral dopaminergic D2 receptors in the gastrointestinal (G.I.) wall, thereby enhancing gastrointestinal peristalsis and motility and increasing Lower Esophageal Sphincter (LES) tone.

RATIONALE OF COMBINATION

The mode of action of both Pantoprazole and Domperidone are different and complimentary to each other. Upper G.I. disorders are frequently associated with a combination of hyperacidity and dysmotility. As a result, acidic chyme may either stagnate in stomach and duodenum or may be evacuated by reverse peristalsis

(vomiting or nausea). Reflux of acid contents of stomach cause erosions of lower part of esophagus which may further aggravate nausea and vomiting. Since both hyperacidity and dysmotility are present at the same time in disorders like Gastro Esophageal Reflux Disease (GERD) and Non Ulcer Dyspepsia (NUD), a combination of drugs which will take care of both would be ideal.

Pantoprazole is a potent gastric acid inhibitor that blocks the final stage of acid secretion. Hence, whatever may be the stimulus, hyperacidity will be controlled by Pantoprazole. In contrast, Domperidone increases G.I. motility, thereby facilitating the movement of acid contents further down in the intestine preventing reflux esophagitis and thereby controlling nausea and vomiting. Hence, the pharmacology of Pantoprazole and Domperidone corroborates their use in combined form for the treatment of GERD, NUD and related disorders.

Domperidone is usually administered at a dose of 10-20 mg, 2-3 times daily before meals. In order to enhance patient compliance, OD-PEP-D has been designed for single dose administration, which contains two smartlets of Domperidone, each containing 10 mg of Domperidone. One of the smartlets (white film coated tablet) provides immediate release of Domperidone whereas the other is in delayed release form. Bioavailability studies conducted on human volunteers have shown biphasic release profile of Domperidone, which allows once daily administration. This helps in improving patient compliance without compromising on the efficacy.

STORAGE AND HANDLING:

OD-PEP-D capsules should be stored below 25 ° C. Protect from light and moisture.

Keep the medicine out of reach of children.

DOSAGE FORM – Hard gelatin capsule

COMPOSITION OF THE FDC –

Each OD-PEP-D capsule contains

Pantoprazole Sodium Sesquihydrate equivalent to Pantoprazole 40mg

Domperidone 10mg IR

Domperidone 10mg SR

PACKAGING – 10 capsules /strip

PART II: SCIENTIFIC INFORMATION

PHARMACEUTICAL INFORMATION

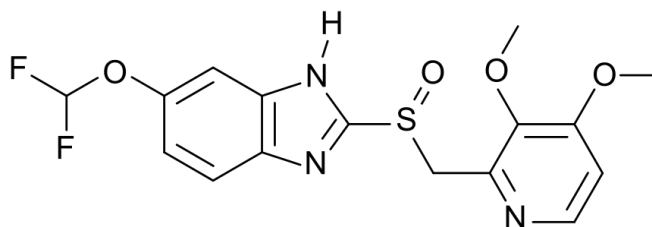
Drug Substance

Common Name: Pantoprazole

Chemical Name:

Sodium 5-(difluoromethoxy)-2-[[[(3,4-dimethoxy-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole sesquihydrate

Pantoprazole has the following chemical structure :



The molecular weight is 383.371 g/mol. The molecular formula is C₁₆H₁₅F₂N₃O₄S

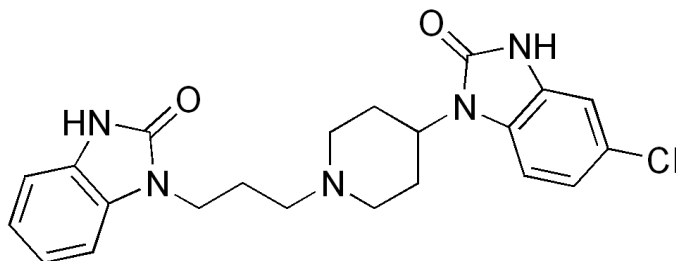
Drug Substance

Common Name: Domperidone

Chemical Name:

5-chloro-1-(1-[3-(2-oxo-2,3-dihydro-1H-benzo[d]imidazol-1-yl)propyl]piperidin-4-yl)-1H-benzo[d]imidazol-2(3H)-one

Domperidone hydrochloride has the following chemical structure :



The molecular weight is 425.911 g/mol. The molecular formula is C₂₂H₂₄ClN₅O₂

CLINICAL TRIALS:

Clinical efficacy of Pantoprazole in GERD

Erosive Esophagitis Associated with GERD

Erosive esophagitis is one of the more serious forms of GERD, a chronic condition caused by the reflux of stomach acid into the esophagus. More than 40% of adults experience GERD symptoms two or more times a week. If left untreated or uncontrolled, esophageal damage caused by GERD may lead to even more serious complications, including stricture, hemorrhage, a precancerous condition known as Barrett's esophagus, and esophageal cancer.

Pantoprazole has been compared with histamine H₂-receptor antagonists (H₂RAs) and omeprazole in clinical trials of patients with grade II or III (Savary-Miller scale) reflux esophagitis (Table 1). Studies comparing pantoprazole and H₂RAs found that pantoprazole had consistently better healing rates and symptom control.

Two well-designed, randomized, double-blind, multicenter trials found 40 mg of pantoprazole once a day and 20 mg of omeprazole once a day clinically equivalent in resolving the endoscopic and symptomatic manifestations of moderate to severe reflux esophagitis. A separate clinical trial examined the pharmacodynamic differences in healthy adults and found that 40 mg of pantoprazole daily exhibited a more rapid on-set of action and superior inhibition of meal-stimulated gastric acid secretion than 20 mg of omeprazole daily. However, to date these pharmacodynamic differences have not translated into a significant difference in the outcome of clinical trials of esophagitis.

Dose-ranging in GERD. A trial by Van Rensburg and colleagues in a group of patients with esophagitis compared the efficacy and tolerability of 40 and 80 mg of pantoprazole daily. Results were reported for protocol-correct patients and found complete healing to be 78% versus 72% after four weeks of therapy and 95% versus 94% after eight weeks of therapy ($p > 0.05$). The authors concluded that 40 and 80 mg were comparable in treating reflux esophagitis. This clinical finding is

consistent with the pharmacodynamic data in a well-designed study of healthy subjects, which suggested that 40 mg was no more effective than 80 or 120 mg with respect to median intragastric pH or the time with pH above 4.

Maintenance therapy for healed erosive esophagitis. More than 90% of patients with erosive esophagitis can be healed using short-term treatment with a PPI, but patients tend to experience a high rate of relapse unless maintenance treatment is provided.

The safety and prophylactic efficacy of 40 mg of pantoprazole once a day were evaluated in a multicenter, open-label, one-year trial of 222 patients whose reflux esophagitis had been healed with omeprazole or pantoprazole. Endoscopically confirmed relapse rates were 2% and 6% at 6 and 12 months, respectively. The only population shift in laboratory variables in this long-term study was a doubling of the median serum gastrin level over the first six months. Fifty-four of 222 (24%) patients experienced adverse events, most commonly diarrhea, nausea, vomiting, and dizziness.

A prospective, double-blind, randomized, multicenter trial evaluated long-term maintenance treatment with either 40 or 20 mg of pantoprazole once a day for up to 12 months in 396 patients with completely healed grade II or grade III esophagitis. Endoscopic relapse rates for the 40-mg and 20-mg doses were 7% versus 16% at 6 months and 19% versus 29% after 12 months of therapy. The authors concluded that 20 mg of pantoprazole once a day represents a safe, effective maintenance regimen for most patients with healed reflux esophagitis. Any debate over the equivalence of these two maintenance regimens is unlikely, since only the 40-mg dose is being marketed in the United States.

Clinical efficacy of Domperidone in GERD

A study involving of 44 patients who received 10 mg domperidone, three times daily, or placebo, the domperidone group exhibited a significant reduction of symptoms of belching, fullness, abdominal distension after meals, and heartburn compared with placebo group.

Another study involving 23 patients having complaints of gastrointestinal distress, received 10 mg domperidone, three times daily, and 18 patients received placebo.

A significantly higher proportion of patients taking domperidone showed symptom relief as compared to placebo. Another parallel group study with 20 patients suffering from dyspepsia, receiving domperidone 10 mg, three times daily, and 20 similar patients receiving placebo showed improvements in symptom scores more with domperidone than with placebo.

REFERENCES :

1. Pantoprazole. In: Therapeutic drugs, vol. 2, Edn. Second, edited by Colin Dollery, pp. 11-14
2. Fitton A; Wiseman L. Pantoprazole: A review of its pharmacological properties and therapeutic use in acid-related disorders. *Drugs* 1995; 51(3):460 - 482
3. Domperidone. In: Therapeutic drugs, vol. 1, Edn. Second, edited by Colin Dollery, pp. D196-199
4. Barone JA, Domperidone: A peripherally acting dopamine 2-receptor antagonist. *The Annals of Pharmacotherapy* 1999, 33(4): 429 - 40.

PART III: PATIENT INFORMATION

OD-PEP-D Capsules

This leaflet is a summary and will not tell you everything about the combination. Contact your doctor or pharmacist if you have any questions about the drug

Generic Name: Pantoprazole / Domperidone (Pronunciation : pan TOE pra zole , dome-PER-i-done)

- **What is Pantoprazole / Domperidone ?**
- **What are the Indications and Usage of Pantoprazole / Domperidone ?**
- **What are the contraindications of Pantoprazole / Domperidone ?**
- **What are the storage conditons of Pantoprazole / Domperidone ?**
- **What are the drug interactionsof Pantoprazole / Domperidone ?**
- **What are the adverse reactionsof Pantoprazole / Domperidone ?**
- **What are the precautions of Pantoprazole / Domperidone ?**
- **What happens if I overdose Pantoprazole / Domperidone ?**
- **What happens if I miss a dose of Pantoprazole/ Domperidone ?**
- **What should I discuss with my healthcare provider before receiving Pantoprazole / Domperidone ?**
- **How is Pantoprazole / Domperidone given ?**
- **Where can I get more information ?**

What is Pantoprazole / Domperidone ?

Pantoprazole

Pantoprazole is in a group of drugs called proton pump inhibitors. Pantoprazole decreases the amount of acid produced in the stomach

Domperidone

Domperidone is a prokinetic agent that increases the movements or contractions of the stomach and bowel.

Indications and Usage

Pantoprazole

Pantoprazole is used to treat symptoms of gastroesophageal reflux disease (GERD) and other conditions involving excessive stomach acid such as Zollinger-Ellison syndrome. Pantoprazole is also used to promote healing of erosive esophagitis (damage to your esophagus caused by stomach acid).

Pantoprazole may also be given with an antibiotic to prevent gastric ulcer caused by infection with helicobacter pylori (H. pylori).

Domperidone

- To treat short lived episodes **nausea** (feeling sick) or **vomiting** (being sick) of less than 48 hours duration.
- To relieve **nausea, fullness, belching, heavy bloated stomach, trapped wind and heartburn** which can happen after a meal for treatment periods of up to 2 weeks. This may be because the stomach's digestive rhythm has slowed down and is not moving food contents in the right direction through the digestive system as efficiently as it needs to.

Contraindications

Pantoprazole sodium

- Pantoprazole Sodium is contra-indicated in patients with known hypersensitivity.

- Pantoprazole Sodium is contra-indicated in pregnancy and during breast feeding.

Domperidone

- Known hypersensitivity to domperidone or any of the excipients.
- Prolactin-releasing pituitary tumour (prolactinoma.)
- Hepatic and/or renal impairment
- Domperidone should not be used when stimulation of gastric motility could be harmful: gastrointestinal haemorrhage, mechanical obstruction or perforation.

Storage and Handling

OD-PEP-D capsules should be stored below 25 ° C. Protect from light. Keep the medicine out of reach of children.

Drug Interactions:

Pantoprazole :

Pantoprazole sodium produces a profound and long lasting inhibition of gastric acid secretion. An interaction with compounds whose absorption is pH dependent may occur. Co-administration of Pantoprazole sodium with ketoconazole or itraconazole may result in a significant decrease in antifungal plasma levels. Therefore individual patients may need to be monitored to determine if a dosage adjustment is necessary when ketoconazole or itraconazole are taken concomitantly with EnBA.

Domperidone:

The main metabolic pathway of domperidone is through CYP3A4. In vitro data suggest that the concomitant use of drugs that significantly inhibit this enzyme may result in increased plasma levels of domperidone. Separate in vivo pharmacokinetic/Pharmacodynamic interaction studies with oral ketoconazole or oral erythromycin in healthy subjects confirmed a marked inhibition of

domperidone' s CYP3A4 mediated first pass metabolism by ketoconazole. Opioids may antagonize the effects of domperidone on gastric emptying

Adverse Reactions

Pantoprazole

The most commonly reported adverse drug reactions, during controlled clinical trials with pantoprazole were headache, insomnia, diarrhoea, abdominal pain, asthenia, flatulence, cough pharyngitis, rhinitis, rash and dry mouth. The majority of adverse events experienced during clinical studies were mild or moderate in severity, and transient in nature.

Domperidone

Immune System Disorder: Very rare; Allergic reaction, including anaphylaxis, anaphylactic shock, anaphylactic reaction and angioedema.

- Endocrine disorder: Rare; increased prolactin levels
- Psychiatric system disorders: Very rare: agitation, nervousness.
- Nervous system disorders: Very rare; extrapyramidal side effects, convulsion, somnolence, headache, Not known; dystonia
- Eye disorders: Not known; Oculogyric crisis
- Cardiac disorders: Not known; Prolongation of QT interval; Not known; Ventricular arrhythmias or sudden cardiac death also occur, Gastro-intestinal disorders: Rare gastrointestinal disorders including very rare transient intestinal cramps, very rare;
- Skin and subcutaneous tissue disorders: Very rare; urticaria, pruritus, rashes
- Reproductive system and breast disorders: Uncommon: breast pain, Rare; galactorrhoea, gynaecomastia, amenorrhoea, Not known; reduced libido.
- Investigations: very rare: liver function test abnormal.

As the hypophysis is outside the blood brain barrier, domperidone may cause an increase in prolactin levels. In rare cases this hyperprolactinaemia may lead to neuro-endocrinological

side effects such as galactorrhoea, gynaecomastia and amenorrhoea. Extrapyramidal side effects are exceptional in adults. These side effects reverse

spontaneously and completely as soon as treatment is stopped. Other central nervous system-related effects of convulsion, agitation, and somnolence also are very rare and primarily reported in infants and children.

Precautions:

Monitor

Assess for allergy symptoms (eg, cough, itching, nasal congestion, rhinitis, sneezing, watery eyes) before and periodically throughout therapy. Monitor pulse and BP periodically during therapy. Monitor patient for dizziness, insomnia, and nervousness. If noted, hold therapy.

Pregnancy Risk Factor: Category B

Pregnancy Implications

There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Lactation

Excretion in breast milk unknown/not recommended

Children

The safety and effectiveness of OD-PEP-D for the treatment of GERD patients < 12 years of age have not been established. The safety and effectiveness of OD-PEP-D for other uses have not been established in pediatric patients.

Overdosage

Pantoprazole sodium

Experience to date with deliberate or accidental overdose is limited. The maximum established exposure has not exceeded 60mg twice daily, or 160mg once daily.

Effects are generally minimal, representative of the known adverse event profile and reversible without further medical intervention. No specific antidote is known. Pantoprazole sodium is extensively protein bound and is, therefore, not dialysable. As in any case of overdose, treatment should be symptomatic and general supportive measures should be utilised.

Domperidone

Symptoms

Overdose has been reported primarily in infants and children. Symptoms of over dosage may include agitation, altered.

What happens if I miss a dose ?

Advise patient that if a dose is missed to take as soon as remembered unless it is nearing time for the next dose. Caution patient to not double the dose to catch up.

What should I discuss with my healthcare provider before taking Pantoprazole/ Domperidone ?

Heartburn is often confused with the first symptoms of a heart attack. Seek emergency medical attention if you have chest pain or heavy feeling, pain spreading to the arm or shoulder, nausea, sweating, and a general ill feeling. You should not use this medication if you are allergic to pantoprazole or to similar medicines such as lansoprazole . esomeprazole . omeprazole . or pantoprazole

To make sure you can safely take rabeprazole, tell your doctor if you have severe liver disease or low magnesium levels in your blood.

Some conditions are treated with a combination of rabeprazole and antibiotics. Use all medications as directed by your doctor. **Read the medication guide or patient instructions provided with each medication.** Do not change your doses or medication schedule without your doctor's advice.

Taking a proton pump inhibitor such as pantoprazole may increase your risk of bone fracture in the hip, wrist, or spine. This effect has occurred mostly in people who have taken the medication long term or at high doses, and in those who are age 50 and older. It is not clear whether pantoprazole is the actual cause of an increased risk of fracture. Before you take this medication, tell your doctor if you have osteoporosis or osteopenia (low bone mineral density).

FDA pregnancy category B. This medication is not expected to be harmful to an unborn baby. Tell your doctor if you are pregnant or plan to become pregnant during treatment. It is not known whether pantoprazole passes into breast milk or if it could harm a nursing baby. Do not use this medication without telling your doctor if you are breast-feeding a baby.

How should I take pantoprazole/ domperidone ?

Take pantoprazole exactly as prescribed by your doctor. Do not take in larger or smaller amounts or for longer than recommended. Follow the directions on your prescription label.

Pantoprazole tablets can be taken with or without food. Pantoprazole oral granules should be taken 30 minutes before a meal.

Do not crush, chew, or break the tablet. Swallow it whole. The enteric-coated pill has a special coating to protect your stomach. Breaking the pill will damage this coating.

Take this medication for the full prescribed length of time. Your symptoms may improve before the infection is completely cleared.

Call your doctor if your symptoms do not improve or if they get worse while you are taking this medicine. Store at room temperature away from moisture and heat.

Where can I get more information?

Your pharmacist can provide more information about pantoprazole/domperidone.