

# <sup>Rx</sup> Pantoprazole Gastro Resistant and Domperidone Prolonged Release Capsules I.P.

**///Pantocise<sup>®</sup>D** पॅन्टोसाईस डी

Each hard gelatin capsule contains:

Pantoprazole Sodium I.P. Equivalent to Pantoprazole (As Gastro Resistant Pellets)	40 mg
Domperidone I.P. (As Prolonged Release Pellets)	30 mg
Excipients	q.s.
Approved colours used in capsule shell.	

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you. Keep this leaflet.

You may need to read it again. If you have any further questions, ask your doctor or nurse. This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours. If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet.

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## Overview

Pantoprazole is proton pump inhibitor (PPI), suppresses the final step in gastric acid (Hydrochloric Acid- HCL).

Domperidone is dopamine (D2) receptor antagonist, produces anti-emetic & gastrokinetic effects. Oral Domperidone increases lower esophageal sphincter (LES) thus improves duodenal motility & accelerate gastric emptying.

Detailed information related to Pantoprazole / Domperidone uses, side-effects, reviews, questions, interactions, and precautions is as follow.

## Uses

Pantoprazole / Domperidone is used for the treatment, control, prevention, & improvement of the following diseases, conditions and symptoms:

- Treatment for Intractable Nausea and Vomiting
- Excess Acid Secretion by Stomach
- Back Flow of Acid from Stomach
- Intestinal or Stomach Ulcers
- Treatment for Symptoms Associated with Idiopathic or Diabetic Gastroparesis
- Heartburn
- Inflammation of Esophagus
- Difficulty in Swallowing

Pantoprazole / Domperidone may also be used for purposes not listed here.

## Side-effects

The following is a list of possible side-effects that may occur in medicines that contain Pantoprazole / Domperidone This is not a comprehensive list. These side-effects are possible, but do not always occur. Some of the side-effects may be rare but serious. Consult your doctor if you observe any of the following side-effects, especially if they do not go away.

- Sensation of whirling and loss of balance
- Increased risk of bone fractures
- Severe Itching of Skin
- Rash Body Temperature
- Diarrhea
- Blurred Vision
- Dizziness
- Headache
- Atrophic gastritis
- Excess of Glucose in the Blood
- General Feeling of Discomfort and Illness
- Pain in Group of Muscles
- Edema
- Hyperlipidemia
- Urinary Frequency
- Flu syndrome
- Drug dependent
- Somnolence
- Akathisia
- Rash
- Pruritus
- Breast Pain
- Irregular Menstruation
- Lactation Disorder
- Asthenia

Pantoprazole / Domperidone may also cause side-effects not listed here.

If you notice other side-effects not listed above, contact your doctor for medical advice.

## Patients with Kidney Problems

If you have kidney problems, you should not take Pantoprazole for eradication of Helicobacter pylori.

## Patients with Liver Problems

If you suffer from severe liver problems, you should not take more than one 20 mg pantoprazole a day (for this purpose containing 20 mg pantoprazole are available).

If you suffer from moderate or severe liver problems, you should not take Pantoprazole for eradication of Helicobacter pylori.

## Precautions

Before using Pantoprazole / Domperidone, inform your doctor about your current list of medications, over the counter products (e.g. vitamins, herbal supplements, etc.), allergies, pre-existing diseases, and current health conditions (e.g. pregnancy, upcoming surgery, etc.). Some health conditions may make you more susceptible to the side-effects of the drug. Take as directed by your doctor or follow the direction printed on the product insert. Dosage is based on your condition. Tell your doctor if your condition persists or worsens. Important counseling points are listed below.

- Be careful before using the medicine if having liver disease and deficiency of vitamin B<sub>12</sub>
- Concurrent use with QT prolongating agents

- Discontinue use if experiencing signs or symptoms associated with cardiac arrhythmia
- Do not take the medicine if you are allergic to it
- Older patients
- Patients with bradycardia
- Patients with cardiac diseases
- Patients with glucose or galactose malabsorption
- Patients with hypokalemia, hyperkalemia or hypomagnesaemia
- Patients with kidney problem

### Interactions with Pantoprazole / Domperidone

If you use other drugs or over the counter products at the same time, the effects of Pantoprazole / Domperidone may change. This may increase your risk for side-effects or cause your drug not to work properly. Tell your doctor about all the drugs, vitamins, and herbal supplements you are using, so that your doctor can help you prevent or manage drug interactions. Pantoprazole / Domperidone may interact with the following drugs and products:

- Amiodarone
- Amprenavir
- Antacids
- Aprepitant
- Atazanavir
- Atropine
- Clarithromycin
- Diltiazem
- Erlotinib
- Erythromycin

### When not to use Pantoprazole / Domperidone

Hypersensitivity to Pantoprazole / Domperidone is a contraindication. In addition, Pantoprazole / Domperidone should not be used if you have the following conditions:

- Atrophic gastritis
- Broken bone
- Clostridium difficile bacteria related colitis
- Co-administration with potent CYP3A4 inhibitors
- Concomitant use with medicines that prolong the QT interval
- Congestive heart failure
- Hypersensitivity to Domperidone
- Low amount of magnesium in the blood

### Other important Information on Pantoprazole/Domperidone

#### Missing a dose

In case you miss a dose, use it as soon as you notice. If it is close to the time of your next dose, skip the missed dose and resume your dosing schedule. Do not use extra dose to make up for a missed dose. If you are regularly missing doses, consider setting an alarm or asking a family member to remind you. Please consult your doctor to discuss changes in your dosing schedule or a new schedule to make up for missed doses, if you have missed too many doses recently.

### Over dosage of Pantoprazole / Domperidone

Do not use more than prescribed dose. Taking more medication will not improve your symptoms; rather they may cause poisoning or serious side-effects. If you suspect that you or anyone else who may have overdosed of pantoprazole / domperidone, please go to the emergency department of the closest hospital or nursing home. Bring a medicine box, container, or label with you to help doctors with necessary information.

Do not give your medicines to other people even if you know that they have the same condition or it seems that they may have similar condition This may lead to overdose.

Pregnant Women: Category C

Lactating Women: Not Recommended

Paediatric Use: Not Recommended

### Expired Pantoprazole / Domperidone

Taking a single dose of expired Pantoprazole / Domperidone is unlikely to produce an adverse event. However, please discuss with your primary health provider or pharmacist for proper advice or if you feel unwell or sick. Expired drug may become ineffective in treating your prescribed conditions. To be on the safe side, it is important not to use expired drugs. If you have a chronic illness that requires taking medicine constantly such as heart condition, seizures, and life-threatening allergies, you are much safer keeping in touch with your primary health care provider so that you can have a fresh supply of unexpired medications.

### How should I store this medicine?

**Storage: Store protected from light and moisture, at a temperature not exceeding 25°C.**

Keep the medicine out of reach of children.

Capsule should be swallowed as whole, and not to be crushed or chewed.

Do not use this medicine after the expiry date which is stated on the carton and the container after expiry. The expiry date refers to the last day of that month.

**Shelf Life:** 24 Months

**Manufactured in India by:**  
**Precise Chemipharma Pvt. Ltd.**

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Marketed by:



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