

Acineu-PD

(Pantoprazole 40 mg & Domperidone 30 mg sustained release Capsules)

Each sustained release capsule contains,

Pantoprazole IP.....40 mg

Domperidone IP.....30 mg (As sustained release pellets)

Excipients.....q.s.

Clinical Pharmacology:

Pantoprazole: Pantoprazole is a proton pump inhibitor (PPI) that reduces the production of stomach acid. It is commonly used to treat conditions like gastroesophageal reflux disease (GERD), peptic ulcer disease, and Zollinger-Ellison syndrome

Domperidone: Works as a gastroprokinetic agent and antiemetic by blocking dopamine receptors, which increases the movement of the stomach and intestines and reduces symptoms of nausea and vomiting.

Indications:

- Gastroesophageal Reflux Disease (GERD) with Delayed Gastric Emptying
- Dyspepsia (Indigestion) with Associated Reflux and Gastroparesis
- Peptic Ulcer Disease with Associated Gastroparesis
- Nausea and Vomiting Associated with Delayed Gastric Emptying

Contraindications:

- Hypersensitivity
- Severe Hepatic Impairment
- Severe Cardiac Risk
- Prolactinoma or Breast Cancer

Precautions and Warnings:

- **Cardiac Monitoring:** Because of domperidone's association with QT prolongation and potential arrhythmias, patients receiving the combination therapy should be monitored for cardiac health, especially those with a history of heart disease, electrolyte imbalances (e.g., hypokalemia, hypomagnesemia), or those taking medications that affect heart rhythm.

- **Liver Function Monitoring:** Since both pantoprazole and domperidone are metabolized by the liver, patients with liver disease should be closely monitored. In cases of moderate to severe hepatic impairment, alternative therapies may be more appropriate.
- **Risk of Increased Domperidone Levels:** Pantoprazole's effects on gastric pH might alter the absorption of certain medications, but the key concern is domperidone's interaction with CYP3A4 inhibitors and other QT-prolonging medications, which increase the risk of serious side effects.
- Elderly patients are at a higher risk of both bone fractures (due to pantoprazole) and cardiac events (due to domperidone). Careful assessment of risks versus benefits is essential in this population.

Drug Interactions:

Additive QT Prolongation Risk:

- While pantoprazole itself does not cause QT prolongation, the combination with domperidone, especially in patients taking other QT-prolonging drugs, can increase the risk of **cardiac arrhythmias**.

Reduced Efficacy of Acid-Dependent Medications:

- Since pantoprazole reduces stomach acid, it may alter the absorption and effectiveness of other medications that depend on an acidic gastric environment. However, this interaction is not specific to domperidone but should be considered if multiple acid-dependent medications are involved.

Adverse Effects:

Increased Cardiac Risk:

- The combination may enhance the risk of **QT prolongation** due to domperidone, especially in patients with underlying cardiac issues or those taking other QT-prolonging medications.

Electrolyte Imbalances:

- Long-term pantoprazole use may lead to **hypomagnesemia**, increasing the risk of cardiac arrhythmias, which can be exacerbated by domperidone's effects on heart rhythm.

Gastrointestinal Effects:

- Potentially increased gastrointestinal disturbances, as both medications can cause nausea, vomiting, and diarrhea.

Overdosage:

Seek emergency medical attention for any suspected overdose, particularly if there are symptoms of severe gastrointestinal distress, cardiac issues, or central nervous system effects.

Route of Administration: The capsules must be swallowed whole, without opening or chewing.

Storage: Store below 25°C in a cool, dry place, away from light and moisture.

Presentation: Supplied as 1 x 10 capsules per strip.

