Ribziff DUO Capsule

Rabeprazole Sodium (E.C.) I.P. 20 mg + Domperidone (S.R.) I.P. 20 mg + Domperidone (I.R.) I.P. 10 mg Capsule

Category: Gastrointestinal / Proton Pump

Inhibitor and Prokinetic Agent

Dosage Form: Capsule

Description:

The Rabeprazole Sodium (E.C.) 20 mg + Domperidone (S.R.) 20 mg + Domperidone (I.R.) 10 mg Capsule is a combination of Rabeprazole, a proton pump inhibitor (PPI), and Domperidone, a prokinetic agent. This formulation is designed to provide effective relief from symptoms related to acid reflux, indigestion, and gastric motility disorders by combining the benefits of acid suppression and improved gastric emptying.

- Rabeprazole is a PPI that reduces stomach acid production, providing relief from conditions such as GERD, gastritis, and peptic ulcers.
- Domperidone is a prokinetic agent that enhances gastric motility and helps in the efficient movement of food through the stomach and intestines. This formulation includes both S.R. (Sustained Release) and I.R. (Immediate Release) forms of Domperidone for a dual action effect. The S.R. form provides a sustained release to improve long-term gastric motility, while the I.R. form ensures rapid relief of nausea and bloating.

Composition (Per Capsule):

- Rabeprazole Sodium (Enteric Coated) I.P.: 20 mg
- Domperidone (Sustained Release)
 I.P.: 20 mg
- Domperidone (Immediate Release) I.P.: 10 mg
- Excipients: Suitable excipients for capsule formulation.

Indications:

This combination medication is used to treat conditions involving both acid reflux and impaired gastric motility, including:

- 1. Gastroesophageal Reflux Disease (GERD):
 - For the treatment of GERD, including symptoms such as heartburn, acid reflux, and regurgitation.
- 2. Peptic Ulcers:
 - To aid in the healing of gastric and duodenal ulcers, and to prevent their recurrence.
- 3. Dyspepsia:
 - For the symptomatic treatment of functional dyspepsia, including bloating, nausea, and discomfort in the upper abdomen.
- 4. Gastritis:
 - For the management of gastritis, including erosive gastritis, by reducing stomach acidity and promoting the healing of the gastric mucosa.

5. Gastroparesis:

 For improving gastric motility in patients with gastroparesis or delayed gastric emptying.

6. Nausea and Vomiting:

 For relief from nausea and vomiting associated with gastrointestinal disorders.

Dosage and Administration:

Adults:

- The recommended dose is 1 capsule (20 mg Rabeprazole + 20 mg Sustained Release Domperidone + 10 mg Immediate Release Domperidone) once daily, preferably before meals.
- The capsule should be swallowed whole with water.
 Do not crush or chew the capsule.

Children:

 The safety and efficacy of this combination for children has not been established. Use is generally not recommended unless specified by a healthcare provider.

• Duration of Treatment:

 The duration of treatment depends on the condition being treated. It is usually recommended for a period of 4-8 weeks for GERD and ulcer healing, while the duration for functional dyspepsia may be shorter. Follow the physician's instructions.

1. Rabeprazole:

Rabeprazole is a proton pump inhibitor that works by irreversibly inhibiting the H+/K+ ATPase enzyme, which is responsible for acid production in the stomach. By inhibiting the proton pump, Rabeprazole effectively reduces the amount of stomach acid, which helps to alleviate symptoms of acid reflux and aids in the healing of acid-induced damage to the stomach lining.

2. Domperidone:

- Domperidone is a dopamine antagonist that acts as a prokinetic agent. It increases the motility of the gastrointestinal tract by enhancing the peristaltic movements of the stomach and intestines, thereby improving gastric emptying and reducing symptoms like bloating and nausea.
- Sustained Release
 Domperidone (S.R.): Provides
 prolonged action, improving
 gastric motility throughout the
 day.
- Immediate Release
 Domperidone (I.R.): Provides
 rapid relief from nausea and
 discomfort by acting quickly to
 enhance gastric emptying.

Contraindications:

• Hypersensitivity:

 Contraindicated in patients with known hypersensitivity to Rabeprazole, Domperidone, or any of the excipients in the formulation.

- Severe Liver Impairment:
 - This combination should not be used in patients with severe liver dysfunction as both Rabeprazole and Domperidone are metabolized in the liver.
- Gastrointestinal Obstruction or Perforation:
 - Contraindicated in patients with intestinal obstruction or perforation, as it may worsen the condition.
- Prolonged QT Interval:
 - Domperidone should not be used in patients with a known prolonged QT interval or other cardiac arrhythmias.

Warnings and Precautions:

1. Liver Disease:

 Use with caution in patients with mild to moderate hepatic impairment. Liver function should be monitored during prolonged treatment with this combination.

2. Cardiac Arrhythmias:

Caution should be exercised in patients with a history of heart disease, especially those with arrhythmias or prolonged QT syndrome, due to the potential for Domperidone to affect the cardiac conduction system.

3. Renal Impairment:

 Domperidone should be used with caution in patients with impaired renal function, as it may accumulate in the body.

4. Pregnancy and Lactation:

 The use of this combination during pregnancy should only be considered if the benefits outweigh the risks.
 Domperidone may pass into breast milk and should be used with caution during breastfeeding.

5. Prolonged Use of PPIs:

 Long-term use of Rabeprazole has been associated with an increased risk of gastric infections, vitamin B12 deficiency, and bone fractures. Use the lowest effective dose for the shortest duration possible.

Adverse Effects:

- Common Side Effects:
 - Headache, dizziness, nausea, dry mouth, abdominal pain, or constipation.
 - Diarrhea or flatulence due to the prokinetic effects of Domperidone.
 - Fatigue, weakness, or mild skin rashes.

• Serious Side Effects:

- Liver enzyme elevation, liver dysfunction, or severe allergic reactions such as angioedema or anaphylaxis.
- Cardiac arrhythmias, including QT prolongation or Torsades de Pointes (rare but possible with Domperidone).
- Severe gastrointestinal symptoms like persistent nausea, vomiting, or abdominal pain.

Drug Interactions:

- Antacids and H2 blockers:
 - The effectiveness of Rabeprazole may be reduced if used with antacids or H2 antagonists due to a potential decrease in its absorption.
- Cytochrome P450 Inhibitors:
 - Rabeprazole is metabolized by the CYP450 enzyme system, so drugs that inhibit these enzymes may increase the blood levels of Rabeprazole.
- Domperidone and CYP3A4 Inhibitors:
 - Domperidone is metabolized by the CYP3A4 enzyme, and drugs that inhibit this enzyme (e.g., ketoconazole, erythromycin) may increase Domperidone levels and the risk of side effects.
- Warfarin:
 - Caution is advised when using Rabeprazole or Domperidone with warfarin or other anticoagulants, as there may be an increased risk of bleeding.

Storage Instructions:

- Store in a cool, dry place at room temperature (15–30°C).
- Keep the medication in its original packaging to protect from moisture.
- Keep out of the reach of children.

- Take the capsule whole and do not crush or chew.
- Regular follow-up with a healthcare provider is recommended during prolonged use.
- If symptoms persist or worsen, further evaluation for underlying conditions is necessary.
- Monitor for signs of liver dysfunction or cardiac side effects, especially with prolonged use.

Note: This combination is intended for symptomatic relief and should be used as directed by a healthcare provider.

Manufactured in India for:



Cafoli Lifecare Pvt. Ltd.

(An ISO 9001: 2015 Certified Co.)

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