Ribziff IT Capsule

Rabeprazole (20 mg) + Itopride (150 mg) Capsule

Category: Gastrointestinal / Proton Pump

Inhibitor and Prokinetic Agent

Dosage Form: Capsule

Description:

The Rabeprazole (20 mg) + Itopride (150 mg) Capsule is a combination therapy used to treat various gastrointestinal disorders. The capsule contains Rabeprazole, a proton pump inhibitor (PPI), and Itopride, a prokinetic agent. This combination works synergistically to treat conditions associated with excessive stomach acid and impaired gastric motility, providing both acid suppression and improved gastric emptying.

- Rabeprazole helps reduce stomach acid production by inhibiting the proton pump in the parietal cells of the stomach. This results in effective relief from acid-related conditions such as acid reflux, gastritis, and peptic ulcers.
- Itopride acts as a prokinetic agent, improving gastric motility and accelerating gastric emptying.
 Itopride is helpful in conditions where gastric motility is impaired, such as functional dyspepsia and gastroesophageal reflux disease (GERD).

- Rabeprazole (as sodium): 20 mg
- Itopride Hydrochloride: 150 mg
- Excipients: Suitable excipients for capsule formulation.

Indications:

This combination medication is used for the treatment of conditions related to both acid reflux and gastric motility disorders, including:

- 1. Gastroesophageal Reflux Disease (GERD):
 - For the management of GERD and related symptoms such as heartburn, regurgitation, and acid reflux.
- 2. Peptic Ulcers:
 - To promote healing of gastric and duodenal ulcers and reduce the risk of ulcer recurrence.
- 3. Functional Dyspepsia:
 - For improving symptoms of dyspepsia, such as bloating, nausea, and upper abdominal discomfort due to impaired gastric emptying.
- 4. Gastritis:
 - For treatment of gastritis, including erosive gastritis, to reduce gastric acidity and promote healing of the stomach lining.
- 5. Acid-Related Disorders:
 - For symptomatic relief from acid-related conditions like

acid reflux, heartburn, and acid indigestion.

Dosage and Administration:

• Adults:

- The typical dose is 1 capsule (20 mg Rabeprazole + 150 mg Itopride) taken once daily before meals.
- The capsule should be swallowed whole with water. It should not be crushed or chewed.

• Duration of Treatment:

o The treatment duration depends on the underlying condition. For example, in GERD, treatment may be extended for several weeks, while for dyspepsia, treatment is often short-term. Follow the doctor's instructions for the duration of use.

Children:

 The use of this combination medication in children is generally not recommended unless specified by a healthcare provider.

Mechanism of Action:

1. Rabeprazole:

 Rabeprazole is a proton pump inhibitor that reduces gastric acid secretion by irreversibly inhibiting the proton pump (H+/K+ ATPase) in the parietal cells of the stomach. This results in decreased stomach acid levels, providing relief from acid-related conditions.

2. Itopride:

Itopride is a prokinetic agent that works by enhancing the motility of the upper gastrointestinal tract. It increases the frequency of gastric contractions and accelerates gastric emptying, thus relieving symptoms of functional dyspepsia and improving the efficiency of the digestive process.

Contraindications:

• Hypersensitivity:

- Contraindicated in individuals who are allergic to Rabeprazole, Itopride, or any excipients in the formulation.
- Severe Hepatic Impairment:
 - Not recommended for use in patients with severe liver dysfunction as Rabeprazole and Itopride are metabolized by the liver.

• Gastrointestinal Obstruction:

 Not suitable for patients with intestinal obstruction or perforation as it may interfere with normal gastrointestinal motility.

Warnings and Precautions:

1. Liver Dysfunction:

 Use with caution in patients with mild to moderate hepatic impairment. Regular monitoring of liver function may be necessary during prolonged treatment.

2. Pregnancy and Lactation:

 The safety of Rabeprazole and Itopride during pregnancy has not been fully established. This combination should only be used during pregnancy if absolutely necessary and under a doctor's supervision. Caution is also advised during breastfeeding.

3. Renal Impairment:

 Use with caution in patients with impaired renal function. Adjustments in dosing may be necessary for individuals with severe renal impairment.

4. Long-Term Use of PPIs:

 Long-term use of Rabeprazole may be associated with an increased risk of fractures, vitamin B12 deficiency, and gastric infections. It should be used at the lowest effective dose for the shortest duration possible.

5. Gastric Malignancy:

 Rabeprazole may mask the symptoms of gastric malignancy. If symptoms of dyspepsia persist or worsen, further evaluation should be performed to rule out malignancy.

Adverse Effects:

Common Side Effects:

 Headache, dizziness, nausea, diarrhea, or constipation.

- Abdominal discomfort or flatulence (due to Itopride's prokinetic effect).
- Dry mouth, taste disturbances, or fatigue.

• Serious Side Effects:

- Liver enzyme elevation or liver dysfunction (rare, but may occur with prolonged use).
- Severe allergic reactions, such as swelling, rash, or difficulty breathing (rare).
- Gastrointestinal disturbances, such as severe abdominal pain, vomiting, or persistent nausea, which may suggest more serious underlying conditions.

Drug Interactions:

Antacids:

- The concurrent use of antacids with Rabeprazole may decrease the absorption of Rabeprazole, although this effect is usually not clinically significant.
- Antibiotics (e.g., Clarithromycin, Rifampin):
 - Rabeprazole may interact with certain antibiotics and affect their metabolism, potentially increasing the risk of side effects.
- Anticholinergic Drugs (e.g., Atropine, Antihistamines):
 - Itopride may interact with other anticholinergic drugs, potentially diminishing the prokinetic effect of Itopride.

• Warfarin:

 Use with caution if the patient is on warfarin or other blood thinners, as Rabeprazole may affect warfarin's metabolism, increasing the risk of bleeding.

- Cytochrome P450 Enzyme Inhibitors:
 - Rabeprazole is metabolized by the CYP450 enzyme system, and certain drugs may interfere with its metabolism, affecting its efficacy and safety.

Storage Instructions:

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

Key Points for Use:

- Rabeprazole + Itopride combination should be used regularly as prescribed for optimal symptom control.
- Do not crush or chew the capsules; swallow them whole.
- It is essential to follow a healthy lifestyle, including diet and exercise, to manage gastrointestinal conditions effectively.
- Monitor for any signs of liver dysfunction or gastrointestinal complications during treatment, particularly for long-term use.
- Consult a healthcare provider if symptoms do not improve or worsen after treatment.

Note: This combination therapy is designed for symptomatic relief and is not suitable for acute ulcer treatment or as a substitute for surgical intervention if necessary.

Manufactured in India for:



(An ISO 9001: 2015 Certified Co.)

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