

(Rabeprazole & Ondansetron Tablets)

Composition:

Each enteric coated tablet Contains:

Rabeprazole... 20mg Ondansetron 4mg Exicipents...q.s.

Clinical Pharmacology:

Rabeprazole

Rabeprazole belongs to a class of antisecretory compounds that suppress gastric acid secretion by inhibiting the gastric H+, K+ ATPase at the secretory surface of the gastric parietal cell. Because this enzyme is regarded as the acid (proton) pump within the parietal cell, rabeprazole has been characterized as a gastric protonpump inhibitor. Rabeprazole blocks the final step of gastric acid secretion.

Ondansetron

Ondansetron is a potent, highly selective 5HT3 receptor-antagonist with central antiemetic effects.

Indications:

- Healing of Erosive or Ulcerative Gastroesophageal Reflux Disease (GERD).
- Post operative nausea and vomiting.
- Radiotherapy and chemotherapy induced nausea and vomiting.
- Gastroenteritis.

Use in special population:

Pediatric Use: Dosage strength not appropriate for patients less than 12 years.

Contraindications:

- Patients with a history of hypersensitivity to rabeprazole
- Proton pump inhibitors, including rabeprazole delayed-release tablets, are contraindicated in patients receiving rilpivirine-containing products
- Concomitant use of apomorphine

Precautions and Warnings:

Gastric Malignancy: In adults, symptomatic response to therapy with rabeprazole does

not preclude the presence of gastric malignancy. Consider additional follow-up and

diagnostic testing

• Use with Warfarin: Monitor for increases in INR and prothrombin time

Acute Interstitial Nephritis: Observed in patients taking proton pump inhibitors

Bone Fracture: Long-term and multiple daily dose proton pump inhibitors therapy may

be associated with an increased risk for osteoporosis-related fractures of the hip, wrist,

or spine.

Hypersensitivity reactions including anaphylaxis and bronchospasm: Discontinue

ondansetron if suspected. Monitor and treat promptly per standard of care until signs

and symptoms resolve.

Drug Interactions:

Decreased exposure of some antiretroviral drugs (e.g., rilpivirine, atazanavir, and nelfinavir)

when used concomitantly with rabeprazole may reduce antiviral effect and promote the

development of drug resistance. Increased exposure of other antiretroviral drugs (e.g.,

saguinavir) when used concomitantly with rabeprazole may increase toxicity

Adverse effects:

Most common adverse reactions in adults are pain, pharyngitis, flatulence, infection,

and constipation

Most common adverse reactions in adolescents are headache, diarrhea, nausea,

vomiting, and abdominal pain

Overdosage:

There are no clinical signs or symptoms associated with any reported overdose.

For Therapeutic Use.

Route of administration: Oral.

Type of tablet: enteric coated Tablet.

Dosage: As directed by Physician.

SCHEDULE H PRESCRIPTION DRUG CAUTION- Not to be sold by retail without the Prescription of

a Registered Medical Practitioner.

Storage:

Store in cool, dry and dark place.

Presentation: Epidor-ON enteric coated tablet available as 10 x 10 Tablets

Marketed By:



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