For the use of registered Medical Practitioner or Laboratory or Pharmacy

AMERICAN
Omeecan 20 ओमीकन २०

Omeprazole Gastro-Resistant Capsules IP 20 mg

Composition :
Each hard gelatin capsule contains :

Omeprazole I.P.	20 mg
(As enteric coated granules)	
Excipients	q.s.

Colour : Approved colour used in empty capsule shells.

Description:
Pink coloured/Clear Transparent size "2" hard gelatin capsule containing white coloured pellets.

ATC Code: A02BC01

Pharmacology:
Pharmacodynamics:
Omeprazole, a racemic mixture of two enantiomers reduces gastric acid secretion through a highly targeted mechanism of action. It is a specific inhibitor of the acid pump in the parietal cell. It is rapidly acting and provides control through reversible inhibition of gastric acid secretion with once daily dosing.
Omeprazole is a weak base and is concentrated and converted to the active form in the highly acidic environment of the intracellular canaliculi within the parietal cell, where it inhibits the enzyme H+ K+-ATPase - the acid pump. This effect on the final step of the gastric acid formation process is dose-dependent and provides for highly effective inhibition of both basal acid secretion and stimulated acid secretion, irrespective of stimulus.

Pharmacokinetics:
Omeprazole is acid labile and are therefore administered orally as enteric-coated granules in capsules. Absorption of omeprazole is rapid, with peak plasma levels occurring approximately 1-2 hours after dose.
The apparent volume of distribution in healthy subjects is approximately 0.3 l/kg body weight. Omeprazole is 97% plasma protein bound.
Omeprazole is completely metabolised by the cytochrome P450 system (CYP). The major part of its metabolism is dependent on the polymorphically expressed CYP2C19, responsible for the formation of hydroxyomeprazole, the major metabolite in plasma. The remaining part is dependent on another specific isoform, CYP3A4, responsible for the formation of omeprazole sulphone.
Omeprazole is excreted as metabolites in the urine, the remainder in the faeces, primarily originating from bile secretion.

Indications:
Omeprazole capsule is indicated in adults and children aged over 1 year of age and ≥ 10 kg. Omeprazole gastro resistant capsules are indicated for:
Adults
- Treatment of duodenal ulcers
- Prevention of relapse of duodenal ulcers
- Treatment of gastric ulcers
- Prevention of relapse of gastric ulcers In combination with appropriate antibiotics, Helicobacter pylori (H. pylori) eradication in peptic ulcer disease
- Treatment of NSAID-associated gastric and duodenal ulcers
- Prevention of NSAID-associated gastric and duodenal ulcers in patients at risk
- Treatment of reflux esophagitis
- Long-term management of patients with healed reflux esophagitis
- Treatment of symptomatic gastro-esophageal reflux disease
- Treatment of Zollinger-Ellison syndrome

Paediatric population
Children over 1 year of age and ≥ 10 kg
- Treatment of reflux esophagitis
- Symptomatic treatment of heartburn and acid regurgitation in gastro-esophageal reflux disease

Children and adolescents over 4 years of age
- In combination with antibiotics in treatment of duodenal ulcer caused by *H. pylori*

Dosage and Administration:
Adults
Treatment of duodenal ulcers: Omeprazole 20 mg capsule once daily.In patients with poorly responsive duodenal ulcer Omeprazole 40 mg capsule once daily.
Prevention of relapse of duodenal ulcers: Omeprazole 20 mg capsule once daily.
Treatment of gastric ulcers: Omeprazole 20 mg capsule once daily. In patients with poorly responsive gastric ulcer Omeprazole 40 mg capsule once daily is recommended.
Prevention of relapse of gastric ulcers: Omeprazole 20 mg capsule once daily. If needed the dose can be increased to Omeprazole 40 mg capsule once daily.
Paediatric population
Children over 1 year of age and 10-20 kg: 10 mg once daily. The dose can be increased to 20 mg once daily if needed.
Children over 2 year of age and 20 kg: 20 mg once daily. The dose can be increased to 40 mg once daily if needed.
Special populations
Impaired renal function: Dose adjustment is not needed in patients with impaired renal function.
Impaired hepatic function: Daily dose of 10–20 mg.

Contraindications:
- Hypersensitivity to Omeprazole, substituted benzimidazoles or to any of the excipients used in the formulation.
- Omeprazole like other proton pump inhibitors (PPIs) must not be used concomitantly with nelfinavir.

Drug Interactions:
Nelfinavir, atazanavir: Concomitant administration of omeprazole with nelfinavir and atazanavir are contraindicated The plasma levels of nelfinavir and atazanavir are decreased in case of co-administration with omeprazole.

Digoxin: Concomitant treatment with omeprazole and digoxin in healthy subjects increased the bioavailability of digoxin by 10%. Digoxin toxicity has been rarely reported.

Clopidogrel: In a crossover clinical study, clopidogrel (300 mg loading dose followed by 75 mg/day) alone and with omeprazole (80 mg at the same time as clopidogrel) were administered for 5 days.

Other active substances: The absorption of posaconazole, erlotinib, ketoconazol and itraconazol is significantly reduced and thus clinical efficacy may be impaired. For posaconazol and erlotinib concomitant use should be avoided.

Side Effects:
The most common side effects (1-10% of patients) are headache, abdominal pain, constipation, diarrhoea, flatulence and nausea/vomiting.

Warnings and Precautions:
In the presence of any alarm symptom (e.g. significant unintentional weight loss, recurrent vomiting, dysphagia, haematemesis or melena) and when gastric ulcer is suspected or present, malignancy should be excluded, as treatment may alleviate symptoms and delay diagnosis.

If the combination of atazanavir with a proton pump inhibitor is judged unavoidable, close clinical monitoring (e.g virus load) is recommended in combination with an increase in the dose of atazanavir to 400 mg with 100 mg of ritonavir; omeprazole 20 mg should not be exceeded.

Pregnancy & Lactation:
Pregnancy
Omeprazole should only be used during pregnancy if clearly indicated and after an accurate benefit/risk evaluation.

Lactation
Omeprazole is excreted in breast milk but is not likely to influence the child when therapeutic doses are used.

Overdose & Treatment:
Symptoms
Overdoses of omeprazole oral doses have reached up to 2,400 mg omeprazole (120 times the usual recommended clinical dose). Nausea, vomiting, dizziness, abdominal pain, diarrhoea and headache may produce.

Treatment
Symptomatic treatment is required.

Storage : Store Protected from light & moisture, at a temperature not exceeding 30°C.

For the use of registered Medical Practitioner or Laboratory or Pharmacy

Presentation:
Strip of 15 capsules & Insert packed in mono carton.
Box of 20x15 capsules

Marketed by:
AMERICAN REMEDIES ©
Care & Cure with Research
American Remedies Healthcare Pvt. Ltd.
(An ISO 9001-2015 Certified Company)
ICO: American Remedies LLC, DE, USA
Gala No. 105 to 111, 1st Flr., Bldg. No. E-15/A,
Harihar Complex, Bhiwandi, Mumbai - 421302
E-mail: info@americanremedies.in