Omecron

Omeprazole

COMPOSITION

Omecron 20 Capsule: Each capsule contains Omeprazole USP 20 mg as enteric coated pellets.
Omecron 40 Capsule: Each capsule contains Omeprazole USP 40 mg as enteric coated pellets.
Omecron 40 IV Injection: Each vial contains sterile lyophilized cake or powder of Omeprazole Sodium BP equivalent to Omeprazole 40 mg and each ampoule contains 10 ml of 0.9% Sodium Chloride BP Injection.

PHARMACOLOGY

Omeprazole is a proton pump inhibitor, reduces gastric acid secretion by specifically inhibiting the gastric enzyme H^+/K^+ ATPase within the parietal cell.

INDICATION

Adults: Both capsule and Injection are indicated in the treatment and prevention of relapse of duodenal and gastric ulcers, *H. pylori* induced in peptic ulcers; treatment and prevention of NSAID-associated gastric and duodenal ulcers (patients at risk); treatment of reflux esophagitis, symptomatic gastro-esophageal reflux disease and long-term management of patients with healed reflux esophagitis. It is also indicated for the treatment of Zollinger-Ellison syndrome.
Children (>1 year of age and ≥ 10 kg body weight): Capsule is indicated for treating reflux esophagitis, symptomatic treatment of heartburn and acid regurgitation in gastroesophageal reflux disease.
Adolescents and children over 4 years of age: Capsule used in combination with antibiotics in treatment of duodenal ulcer caused by *H. pylori.*
There is limited experience with the use of Omeprazole IV in children.

DOSAGE AND ADMINISTRATION

Capsule

Adults

Duodenal ulcers, gastric ulcers and NSAID-associated gastric and duodenal ulcers, 20 mg once daily. In most patients healing occurs within 2 weeks (healing time for gastric ulcers and NSAID-associated ulcers is 4 weeks); requires a further two weeks (4 weeks for gastric ulcers and NSAID-associated ulcers) if not healed fully after the initial treatment. For poorly responsive duodenal ulcers and gastric ulcers 40 mg once daily for four weeks (8 weeks for gastric ulcers). For the prevention of relapse, 20 mg once daily (*H. pylori* negative patients); if needed this dose can be increased to 40 mg for the prevention of relapse of gastric ulcers and duodenal ulcers.
***H. pylori* eradication in peptic ulcer disease:** Oral Omeprazole along with antimicrobials (Amoxicillin, Clarithromycin, Metronidazole, Tinidazole) for one week is recommended. If the patient is still *H. pylori* positive, therapy may be repeated.
Reflux esophagitis: 20 mg once daily for 4 weeks; required further four weeks if not healed fully after the initial treatment. For severe esophagitis, 40 mg once daily for 8 weeks. For long-term management of healed reflux esophagitis, 10 mg once daily; if needed, the dose can be increased to Omeprazole 20 to 40 mg once daily.
Symptomatic gastro-oesophageal reflux disease: 10-20 mg once daily depending on patient response. If symptom control is not achieved after 4 weeks with 20 mg dose, further investigation is recommended.
Zollinger-Ellison syndrome: Dose should be individually adjusted and treatment should continue as long as clinically indicated. The initial dose is 60 mg daily. When the dose exceeds Omeprazole 80 mg daily, the dose should be divided and given twice daily.

Children

≥ 1 year of age and 10-20 kg: 10 mg once daily; 20 mg once daily if needed.
≥ 2 years of age and >20 kg: 20 mg once daily; 40 mg once daily if needed.
For reflux esophagitis, treatment duration is 4-8 weeks.
For symptomatic treatment of heartburn and acid regurgitation in gastro-oesophageal reflux disease, the treatment duration is 2-4 weeks. If symptom control has not been achieved after 2-4 weeks, the patient should be investigated further.
Adolescents and children over 4 years of age: For duodenal ulcers caused by *H.pylori*, select appropriate antimicrobial therapy along with Omeprazole.

Injection

In patients where the use of oral therapy is inappropriate, 40 mg IV once daily is recommended. In patients with Zollinger-Ellison syndrome, the recommended initial intravenous dose is 60 mg daily. Higher daily doses may be required and the dose should be adjusted individually. When doses exceed 60 mg daily, the dose should be divided and given twice daily.
In patients with impaired hepatic function, a daily dose of 10-20 mg may be sufficient.

Preparation and administration

For reconstitution, sodium chloride 9 mg/ml (0.9%) solution or glucose 50 mg/ml (5%) solution must be used as an infusion solution. For that draw 5 ml of infusion solution with a syringe from the 100 ml infusion bottle or bag. Then add this volume to the Omeprazole vial and mix thoroughly making sure all Omeprazole is dissolved. Draw the Omeprazole solution back into the syringe and then transfer the solution into the infusion bag or bottle. Immediately after reconstitution, Omeprazole is to be administered in an intravenous infusion for 20-30 minutes.

CONTRAINDICATION

It is contraindicated in hypersensitivity to Omeprazole, substituted Benzimidazoles or any other ingredients of it.

WARNING & PRECAUTION

Gastric Malignancy: Symptomatic response with Omecron does not preclude the presence of gastric malignancy. Consider additional follow-up and diagnostic testing.
Acute Tubulointerstitial Nephritis: Discontinue treatment and evaluate patients.
Cyanocobalamin (Vitamin B12) deficiency: Daily long-term use (longer than 3 years) may lead to malabsorption or a deficiency of Cyanocobalamin.
Bone Fracture: Long-term and multiple daily dose PPI therapy may be associated with an increased risk for osteoporosis-related fractures of the hip, wrist or spine.
Severe Cutaneous Adverse Reactions: Discontinue at the first signs or symptoms.
Subacute Cutaneous Lupus Erythematosus (SCLE): Discontinue Omecron and refer to a specialist for evaluation.
Hypomagnesemia: Reported rarely with prolonged treatment with PPIs.
Interactions with Diagnostic Investigations for Neuroendocrine Tumors: Temporarily stop Omecron at least 14 days before assessing CgA levels.

SIDE EFFECT

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

USE IN PREGNANCY & LACTATION

There was no evidence of an adverse effect on fertility. It can be used during pregnancy. Omeprazole is excreted in breast milk but is not likely to influence the child when the therapeutic dose is used.

USE IN CHILDREN & ADOLESCENTS

There is no experience with Omeprazole IV in children.

DRUG INTERACTION

Diazepam: Consideration should be given to a reduction in diazepam dosage when Omeprazole IV is co-prescribed.
Phenytoin: Monitoring of patients receiving phenytoin is recommended and a reduction of the phenytoin dose may be necessary.
Antiretroviral drugs (Rilpivirine, Atazanavir and Nelfinavir): Concomitant use may reduce the antiviral effect and promote the development of drug resistance.
Saquinavir: Concomitant use may increase the toxicity.
Warfarin: Concomitant use may increase INR and prothrombin time.
Methotrexate: Concomitant use may elevate and prolong serum concentrations of methotrexate and/or its metabolite.
Clopidogrel: Concomitant use resulted in reduced plasma concentrations of the active metabolite of clopidogrel and a reduction in platelet inhibition.
Cilostazol: Increased exposure of cilostazol and one of its active metabolites.
Digoxin: Potential for increased exposure of digoxin.
St. John's Wort and Rifampin: Decrease the Omeprazole concentration.
Iron salts, Erlotinib, Dasatinib, Nilotinib, Mycophenolate Mofetil, Ketoconazole/Itraconazole: Can reduce the absorption of these drugs due to its effect on reducing intragastric acidity.
Tacrolimus: Potentially increased exposure of tacrolimus, especially in transplant patients who are intermediate or poor metabolizers of CYP2C19.

OVERDOSAGE

In suspected cases of overdosage, treatment should be supportive and symptomatic.

STORAGE

Store below 30°C temperature in a cool and dry place. Protect from light and moisture. Keep out of the reach of children.

HOW SUPPLIED

Omecron 20 Capsule: Each box contains 50 capsules in Alu-Alu blister pack.
Omecron 40 Capsule: Each box contains 40 capsules in Alu-Alu blister pack.
Omecron 40 IV Injection: Each combipack contains one vial containing sterile lyophilized cake or powder of Omeprazole Sodium BP equivalent to Omeprazole 40 mg and one ampoule of 10 ml 0.9% Sodium Chloride BP Injection. It also contains a sterile disposable syringe (10 ml).

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NIPRO JMI Pharma

Manufactured by:
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