

OmentaTM

Omeprazole

Composition:

OmentaTM 20 Capsule: Each capsule contains Omeprazole BP 20 mg.

OmentaTM IV injection: Each vial contains lyophilized powder of Omeprazole Sodium BP equivalent to Omeprazole 40 mg.

Description:

OmentaTM suppresses gastric acid secretion by specific inhibition of H⁺/K⁺ ATPase enzyme system at the secretory surface (final step of acid production) of the gastric parietal cell. This effect is dose related & leads to inhibition of basal & stimulated acid secretion irrespective of stimulus. After oral administration the onset of anti secretory effects of **OmentaTM** occurs within one hour with the maximum effect occurring within 2 hours & inhibition of secretion lasts up to 17 hours. When the drug is discontinued, the secretory activity returns gradually over 3-5 days.

Indications:

OmentaTM capsule is indicated in the treatment of –

- Esophageal reflux disease
- Heart burn & or epigastric pain associated with acid-related dyspepsia
- Duodenal & benign gastric ulcers including those complicating NSAID therapy
- Zollinger-Ellison syndrome
- Treatment of prophylaxis of NSAID-associated benign gastric ulcers, duodenal ulcers & gastroduodenal erosion in patients with a previous history of gastroduodenal lesions who require continued NSAID treatment
- Relief of associated dyspeptic symptoms
- Prophylaxis of acid aspiration
- Eradication of *Helicobacter Pylori*

OmentaTM IV injection is indicated for the treatment of-

- Gastric ulcer
- Duodenal ulcer
- Reflux esophagitis
- Zollinger-Ellison syndrome

Dosage & Administration:

OmentaTM capsule:

It should be taken 15-30 minutes before meal.

Duodenal ulcer: 20 mg once daily for 4 weeks. In severe cases 40 mg once daily.

Benign gastric ulcer: 20 mg once daily for 8 weeks. In severe cases 40 mg once daily.

NSAIDs induced peptic ulcer and gastroduodenal erosions: 20 mg once daily for 4 weeks, followed by a further 4 weeks if not fully healed.

Prophylaxis in patients with a history of NSAIDs associated gastroduodenal lesions who require continued NSAID treatment: 20 mg once daily.

Gastro-esophageal reflux disease: 20 mg once daily for 4 weeks for those not fully healed, to be continued for another 4 weeks.

Gastro-esophageal reflux disease refractory to other treatment: 40 mg once daily for 8 weeks may be continued at 20 mg once daily.

Acid reflux disease for long term management: 10 mg daily, increasing to 20 mg once daily if symptoms return.

Acid related dyspepsia: 10-20 mg once daily for 2-4 weeks according to response.

Gastric acid reduction during general anesthesia (Prophylaxis of acid aspiration): 40 mg on the preceding evening then 40 mg 2-6 hours before surgery.

Zollinger-Ellison Syndrome: Initially 60 mg once daily; usual range 20-120 mg daily (above 80 mg in 2 divided dosage).

Maintenance for recurrent duodenal ulcer: 20 mg once daily.

Prevention of relapse in duodenal ulcer: 10 mg daily increasing to 20 mg once daily if symptoms return.

Eradication of Helicobacter Pylori: Omeprazole 20 mg twice daily plus Amoxicillin 500 mg four times daily plus Metronidazole 400 mg thrice daily for 2 weeks.

Impaired hepatic function: As bioavailability and half-life can be increased in patient with impaired hepatic function. The dose requires adjustment with a maximum daily dose of 20 mg.

OmentaTM IV Injection:

In patients with duodenal ulcer, gastric ulcer or reflux esophagitis: 40 mg once daily is recommended.

In patients with Zollinger-Ellison syndrome: the recommended initial 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.

Impaired renal function: Dose adjustment is not needed in patients with impaired renal function.

Impaired hepatic function: As plasma half-life of Omeprazole is increased in patients with impaired hepatic function, a daily dose of 10 - 20 mg may be sufficient.

Elderly: Dose adjustment is not needed in the elderly.

Children: The safety and effectiveness of Omeprazole injection in children have not yet been established.

OR AS DIRECTED BY THE PHYSICIAN.

Side Effects:

Omeprazole is generally well tolerated. Nausea, diarrhoea, flatulence, abdominal pain, constipation, dizziness and headache have been reported but are rare. Skin rashes have occurred in a few patients. These events have usually been mild & transient & there has been no consistent relationship with treatment.

Precautions:

Before treatment the presence of gastric malignancy should be excluded.

Contraindications:

Omeprazole is contraindicated in patients with known hypersensitivity to any component of the formulation.

Storage Condition:

Store in a cool & dry place for capsule & 25°C for injection, protect from light. Keep out of the reach of children.

Presentation:

OmentaTM 20 Capsule: Each box contains 10x10's capsules in blister pack.

OmentaTM IV injection: Each box contains 1 combipack and a 10 ml sterile disposable syringe. Each combipack contains 1 vial and 1 ampoule of 10 ml Water for injection BP.

OmentaTM 20 capsule

Manufactured by:

Julphar Bangladesh Ltd.

Sreepur, Gazipur, Bangladesh.

OmentaTM IV Injection

Manufactured by:

Popular Pharmaceuticals Ltd. for

Julphar Bangladesh Ltd.

Sreepur, Gazipur, Bangladesh.