Ometor

Omeprazole BP

COMPOSITION :

Ometor 20 mg Capsule: Each capsule contains Omeprazole BP 20 mg as enteric coated Pellets.
Ometor 40 mg IV injection: Each vial contains sterile Omeprazole sodium BP equivalent to 40 mg omeprazole.

PHARMACOLOGY:

Ometor (Omeprazole) a substituted benzimidazole, is an inhibitor of gastric acid secretion. Omeprazole inhibits secretion of gastric acid by blocking the hydrogen-potassium-adenosine triphosphatase enzyme system, the so called 'Proton Pump' of the gastric parietal cell. It is an effective treatment for gastric and duodenal ulcers and particularly for erosive reflux esophagitis. Orally administered Omeprazole is absorbed rapidly but to a variable extent. Following absorption Omeprazole is almost completely metabolized and rapidly eliminated mostly in the urine. Although the elimination half-life from plasma is short, being reported to be 0.5 to 1.5 hours, its duration of action with regard to inhibition of acid secretion is much longer and it is suggested that its distribution to the tissues particularly to the gastric parietal cells accounts for this action. Omeprazole is highly bound (about 95%) to plasma proteins.

INDICATION:

Ometor capsule is indicated for gastroesophageal reflux disease including reflux esophagitis, acid reflux disease, duodenal and benign gastric ulcers, Helicobacter pylori eradication in peptic ulcer disease, prophylaxis of acid aspiration, Zollinger-Ellison Syndrome (ZES) and for the treatment of NSAID-associated gastric ulcers, duodenal ulcers or gastroduodenal erosions.

DOSAGE AND ADMINISTRATION:

Capsule & Tablet: Omeprazole should be taken before meal.

Gastroesophageal reflux disease The usual dosage is 20 mg Omeprazole once daily. The majority including reflux esophagitis of patients are healed after 4 weeks. For those patients not fully healed after the initial course, healing usually occurs during a further 4-8 week treatment. Omeprazole has also been used in a dose of 40 mg daily in patients with reflux esophagitis refractory to other therapy. Healing usually occurred within 8 weeks. Patients can be continued at a dosage of 20 mg once daily. Acid reflux disease for long-term management, Omeprazole 10 mg once daily is recommended, increasing to 20 mg if symptoms return. Duodenal and benign gastric ulcers. The usual dose is 20 mg Omeprazole once daily. The majority of patients with duodenal ulcer are healed after 4 weeks. The majority of patients with benign gastric ulcer are healed after 8 weeks. In severe or recurrent cases the dose may be increased to 40 mg Omeprazole daily. Long-term therapy for patients with a history of recurrent duodenal ulcer is recommended at a dosage of 20 mg Omeprazole once daily. For prevention of relapse in patients withduodenal ulcer, the recommended dose is Omeprazole 10 mg once daily, increasing to 20 mg once if symptoms return. Helicobacter pylori eradication Omeprazole is recommended at a dose of 40 mg once daily or 20 mg in peptic ulcer disease twice daily in association with antimicrobial agents Amoxicillin 1 g and Clarithromycin 500 mg both twice a day for 7 to 14 days. Prophylaxis of acid aspiration For patients considered to be at risk of aspiration of the gastric contents during general anaesthesia, the recommended dosage is Omeprazole 40 mg on the evening before surgery followed by Omeprazole 40 mg 2-6 hours prior to surgery. Zollinger-Ellison syndrome The recommended initial dosage is 60 mg Omeprazole once daily. The dosage should be adjusted individually and treatment continued as long as clinically indicated. More than 90% of patients with severe disease and inadequate response to other therapies have been effectively controlled on doses of 20-120 mg daily. With doses above 80 mg daily, the dose should be divided and given twice daily.

IV INJECTION: Duodenal ulcer, gastric ulcer or reflux esophagitis: in patients with Duodenal ulcer, gastric ulcer or reflux esophagitis where oral medication is inappropriate, Omeprazole IV 40 mg once daily is recommended.

Zollinger-Ellison-Syndrome (ZES): In patients with Zollinger-Ellison-Syndrome (ZES) that recommended initial dose of omeprazole given intravenously 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.

CHILDREN:

GERD or other acid-related disorder:

Age	Body Weight	Dose
> 1 year	10-20 kg	10 mg once daily, if needed, 20 mg once daily.
> 2 years	> 20 kg	20 mg once daily, if needed, 40 mg once daily.

PRECAUTION:

Symptomatic response to therapy with Omeprazole does not preclude the presence of gastric malignancy.

USE IN PREGNANCY AND LACTATION:

Results from three prospective epidemiological studies indicate no adverse effects of Omeprazole on pregnancy or on the health of the fetus/newborn child. Omeprazole can be used during pregnancy. Omeprazole is excreted in breast milk but is not likely to influence the child when therapeutic doses are used.

SIDE EFFECT:

Omeprazole is well tolerated. Nausea, diarrhoea, abdominal colic, paresthesia, dizziness and headache have been stated to be generally mild and transient and not requiring a reduction in dosage.

DRUG INTERACTION :

Omeprazole can delay the elimination of diazepam, phenytoin and warfarin. Reduction of warfarin or phenytoin dose may be necessary when Omeprazole is added to treatment. There is no evidence of interaction with theophylline, propranolol or antacids.

STORAGE CONDITION:

Store in a cool (below 25^{o}c) and dry place, protected from light.

HOW SUPPLIED:

Ometor 20 mg Capsule : Box containing 10 X 10's capsule in Alu-Alu Blister strip.
Ometor 20 mg Capsule : Box containing 6 X 10's capsule in Alu-Alu Blister strip.
Ometor 40 mg Injection : Each combipack contains 1 vial of 40 mg Omeprazole & 1 ampule of 10 ml sterile 0.9% sodium chloride BP Injection.

Manufactured by:

Astra
Biopharmaceuticals Ltd.
Gouripur, Ashulia, Dhaka, Bangladesh