OMEX Capsule

Omeprazole BP

PRESENTATION AND COMPOSITION :

Omex-20 Capsule: Box containing 10 strips of 6 capsules. Each capsule contains Omeprazole enteric coated pellets 240 mg equivalent to Omeprazole BP 20 mg.

Omex-40 Capsule: Box containing 5 strips of 4 capsules. Each capsule contains Omeprazole enteric coated pellets 480 mg equivalent to Omeprazole BP 40 mg.

MECHANISM :

Omeprazole is the first drug to be marketed in a group of agents which reduce gastric acid secretion by inhibition H^+/K^+ATPase (the 'proton pump') of the parietal cell. These agents are the most potent inhibitors of gastric acid secretion.

INDICATIONS AND USES :

Omeprazole is indicated where suppression of acid secretion is of therapeutic benefit.
It may be used for short and long term therapy in -
i) Duodenal ulcer ii) Gastric ulcer iii) Reflux esophagitis and esophageal ulceration iv) Maintenance of healing of erosive esophagitis v) Pathological hypersecretory conditions (e.g. Zollinger-Ellison Syndrome, multiple endocrine adenomas and systemic mastocytosis) vi) Resistant peptic ulcer vii) Eradication of *Helicobacter pylori* in combination with antibiotics.

DOSAGE AND ADMINISTRATION :

Benign gastric and duodenal ulcer : 20 mg once daily for 4 weeks in duodenal ulceration or 8 weeks in gastric ulceration; in severe or recurrent cases increase to 40 mg daily; maintenance for recurrent duodenal ulcer, 20 mg once daily if symptoms return. NSAID-associated duodenal or gastric ulcer and gastroduodenal erosion: 20 mg once with a history of NSAID-associated duodenal or gastric ulcers, gastroduodenal lesion or dyspeptic symptoms who require continued NSAID treatment, 20 mg once daily.

Duodenal ulcer associated with *Helicobacter pylori* : Omeprazole 20 mg twice daily with Clatithromycin 500 mg twice daily and Metronidazole 400 mg twice daily can be used. Omeprazole 20 mg twice daily may also be used in combination with Amoxicillin 1 g twice daily and Clarithromycin 500 mg twice daily. Omeprazole may also be used with Amoxicillin 1 g twice daily and Metronidazole 400 mg twice daily.

Benign gastric ulcer associated with *H. pylori:* Omeprazole 40 mg daily in 1-2 divided doses (plus Amoxicillin 0.75-1 g twice daily) for 2 weeks & also Metronidazole 400 gm twice daily to recover from anaerobic infection.

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

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

Gastroesophageal Reflux disease : 20 mg once daily has been given for 8 weeks, followed by a further 4-8 weeks if not fully healed; 40 mg once daily has been given for 8 weeks in gastroesophageal reflux disease refractory to other teratment, may be continued at 20 mg once daily.

Acid reflux disease (long term management) : 20 mg daily increasing to 40 mg once daily if symptoms return.

Acid-related dyspepsia : 20-40 mg once daily for 2-4 weeks according to response. Child over 2 years, severe ulcerating reflux esophagitis, 0.7-1-4 mg / kg daily for 4-12 weeks maximum 40 mg daily (to be initiated by hospital pediatrician).

COUNSELING: Swallow whole or open capsule and mix contents with fruit juice.

CONTRA INDICATIONS :

Omeprazole is contraindicated in patients with known hypersensitivity to the drug.

PRECAUTION :

Proton pump inhibitors should be used with caution in patients with liver disease and before treatment the presence of gastric malignancy should be excluded.

SIDE EFFECTS :

Side effects of the proton pump inhibitors include headache, abdominal pain, bronchospasm, muscle and joint pain, blurred vision, depression and dry mouth.

DRUG INTERACTION :

Anticoagulant : The effects of warfarin is enhanced by omeprazole.
Antiepileptics : The effects of phenytoin is enhanced by omeprazole.
Anxiolytics and Hypnotics : The metabolism of diazepam is inhibited by omeprazole.
Cardiac glycoside : Plasma concentration of digoxin is possibly increased.
Tacrolimus : Omeprazole possibly increases plasma tacrolimus concentration.

OVER DOSAGE :

Drowsiness resulted, but no serious consequence observed.
A dose of 200 mg intravenously over 24 hours has been given without adverse sequelae.

MANUFACTURED BY :

KEMIKO PHARMACEUTICALS LTD.
Bangladesh