

**Composition : Cosec 20mg Capsule :** Each delayed release capsule contains Omeprazole USP 20mg as coated granules.

**Cosec 40mg Capsule :** Each delayed release capsule contains Omeprazole USP 40mg as coated granules.

**Pharmacology :** Omeprazole belongs to a class of antisecretory compounds, the substituted benzimidazoles, that suppress gastric acid secretion by specific inhibition of the H<sup>+</sup>/K<sup>+</sup> ATPase enzyme system at the secretory surface of the gastric parietal cell. Because this enzyme system is regarded as the acid (proton) pump within the gastric mucosa, omeprazole has been characterized as a gastric acid-pump inhibitor, in that it blocks the final step of acid production.

**Indications :**

Healing of erosive reflux esophagitis.

Zollinger - Ellison syndrome.

For the treatment of gastric ulcers.

For the treatment of duodenal ulcers.

**Dosage & Administration : Erosive Reflux Esophagitis :** The recommended dosage is one 20mg **Cosec** capsule once daily before meal, given for 4 weeks. For those patients not fully healed after the initial course, healing usually occurs during a further 4 weeks treatment.

**Patients With Reflux Esophagitis Refractory to Other Therapy :**

The recommended dosage is 40mg **Cosec** once daily before meal. Healing usually occurs within 8 weeks.

**Duodenal Ulcer :** The usual dose is one 20mg **Cosec** capsule once daily, before meal for 4 weeks. In severe cases the dose may be increased to 40mg **Cosec** capsule once daily before meal.

**Gastric Ulcer :** The usual dose is one 20mg **Cosec** capsule once daily before meal for 8 weeks. In severe cases, the dose may be increased to 40mg **Cosec** capsule once daily. Long-term maintenance treatment with **Cosec** capsule is not recommended.

**Zollinger-ellison Syndrome :** The recommended initial dosage is 60mg (40mg + 20mg) once daily before meal. 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 20mg - 120mg daily. With doses above 80mg daily, the dose should be divided and given twice daily.

**COSEC**

Capsule



**DRUG  
INTERNATIONAL  
LTD.**

**Elderly :** Dose adjustment is not required in the elderly.

**Children :** There is no experience of the use of **Cosec** capsule in children.

**Impaired Renal or Hepatic Function :** Dose adjustment is not required in patients with impaired renal or hepatic function. Patients with severe liver disease should not require more than one 20mg **Cosec** daily. Or, as directed by a registered physician.

**Contra-indication :** **Cosec** delayed release capsules are contraindicated in patients with known hypersensitivity to any component of the formulation.

**Precautions :** Exclude the possibility of malignancy when gastric, ulcer is suspected and before treatment for dyspepsia. When using in combination with antibiotic, refer to the prescribing information of the respective antibiotics.

**Side-effects :** **Cosec** delayed release capsules are well tolerated. Nausea, headache, diarrhoea, constipation, flatulence and skin rashes may occur rarely.

**Use in pregnancy and lactation :** There are no controlled data in women pregnancy. It can be used in pregnancy if potential benefits outweigh the risk or as directed by the registered physician. Omeprazole is likely to be excreted into the breast milk. A decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the benefit of the drug to the mother.

**Use in Child :** No data available.

**Drug Interactions :** Omeprazole can prolong the elimination of diazepam, warfarin and phenytoin, drugs that are metabolized by oxidation in the liver.

**Overdose :** No data available.

**Storage :** Store below 30°C in a dry place.

**Packing : Cosec 20mg Capsule :** Each box contains 5 x 10's capsules in blister pack.

**Cosec 40mg Capsule :** Each box contains 6 x 7's capsules in blister pack.