

**Composition :** Omeprazole 20mg, 40mg Capsule & 40mg injection.

**Indications :**

Healing of erosive reflux oesophagitis.

Zollinger - Ellison syndrome.

For the treatment of gastric ulcers.

For the treatment of duodenal ulcers.

**Dosage & administration : For Capsule :**

**Erosive Reflux Oesophagitis :** 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 Oesophagitis 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-Elison 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.

**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.

**For injection :** In patients with duodenal ulcer, gastric ulcer or reflux oesophagitis where oral medication is inappropriate, Cosec 40mg once daily is recommended. In patients with Zollinger-Elison syndrome the recommended initial dose of Cosec given intravenously is 60mg daily. When doses exceed 60mg daily. The dose should be divided and given twice daily.

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

## Cosec

Cap. / Inj.

**Impaired Hepatic Function :** As plasma half-life of Omeprazole is increased in patients with impaired hepatic function a daily dose of 10-20mg may be sufficient. Or, as directed by the registered physician.

**Method of Administration :** Cosec-40 IV injection should be given as a slow intravenous injection. The solution for IV injection is obtained by adding to the vial 10ml of the solvent provided. After reconstitution the injection should be given slowly over a period of at least 2.5 minutes at a maximum rate of 4ml per minute. The solution should be used within 4 hours of reconstitution.

**For Infusion :** For IV infusion ready to use containing 10 ml of sterile 0.9% sodium chloride solution to make 10ml solution. Subsequently add 10ml reconstituted solution containing 4mg/ml of Omeprazole to further diluted 90ml normal saline or 90ml of 5% Dextrose solution. The resulting infusion should be given intravenously over a period of 20 to 30 minutes. The solution should be used within 12 hours when omeprazole is dissolved in saline and within 6 hours when dissolved in 5 % dextrose.

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

**Use in pregnancy and lactation :** Omeprazole has been assigned to pregnancy category C by the FDA.

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

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

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

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

**Cosec 40mg Injection :** Combipack.