

Seclo®

Omeprazole

COMPOSITION: Seclo® 20 Capsule: Each capsule contains Omeprazole BP 20 mg as enteric coated granules. Seclo® 40 Capsule: Each capsule contains Omeprazole BP 40 mg as enteric coated granules. Seclo® DR 20 Tablet: Each delayed release tablet contains Omeprazole magnesium INN equivalent to Omeprazole 20 mg. Seclo® 40 IV Injection: Each vial contains Omeprazole 40 mg (as lyophilized powder of Omeprazole sodium BP) and each ampoule contains 10 ml of water for injection BP.

PHARMACOLOGY: 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: Seclo® capsule and tablet 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.

Seclo® 40 IV injection is indicated primarily for the treatment of Zollinger-Ellison syndrome, and may also be used for the treatment of gastric ulcer, duodenal ulcer and reflux esophagitis.

DOSAGE AND ADMINISTRATION: Capsule and tablet: Omeprazole should be taken before meal.

Disease	Dosage and administration
Gastroesophageal reflux disease including reflux esophagitis	The usual dosage is 20 mg Omeprazole once daily. The majority 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 weeks treatment. Omeprazole has also been used in a dose of 40 mg once 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 with duodenal ulcer, the recommended dose is Omeprazole 10 mg once daily, increasing to 20 mg once daily if symptoms return.
<i>Helicobacter pylori</i> eradication in peptic ulcer disease	Omeprazole is recommended at a dose of 40 mg once daily or 20 mg 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.
For the treatment of NSAID-associated gastric ulcers, duodenal ulcers or gastroduodenal erosions	The recommended dosage of Omeprazole is 20 mg once daily. Symptom resolution is rapid and in most patients healing occurs within 4 weeks. For those patients who may not be fully healed after the initial course, healing usually occurs during a further 4 weeks treatment. For the prophylaxis of NSAID-associated gastric ulcers, duodenal ulcers, gastroduodenal erosions and dyspeptic symptoms in patients with a previous history of gastroduodenal lesions who require continued NSAID treatment, the recommended dosage of Omeprazole is 20 mg once 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 the 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 disorders	Age	Body Weight	Dose
	> 1 year	10 - 20 kg	10 mg once daily, if needed, 20 mg once daily
	> 2 year	> 20 kg	20 mg once daily, if needed, 40 mg once daily

Impaired renal function: Dosage adjustment is not necessary.

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

Elderly: Dosage adjustment is not necessary.

Children: There is limited experience with Omeprazole IV injection.

DIRECTION FOR USE OF IV INJECTION: Omeprazole lyophilized powder and water for injection is for intravenous administration only and must not be given by any other route.

Omeprazole IV injection should be given as a slow intravenous injection. The solution for IV injection is obtained by adding 10 ml water for injection to the vial containing powder. After reconstitution the injection should be given slowly over a period of at least 2 to 5 minutes at a maximum rate of 4 ml/minute. Use only freshly prepared solution. The solution should be used within 4 hours of reconstitution.

DIRECTION FOR USE OF IV INFUSION: Omeprazole IV infusion should be given as an intravenous infusion over a period of 20-30 minutes or more. The contents of one vial must be dissolved in 100 ml saline for infusion or 100 ml 5% Dextrose for infusion. The solution should be used within 12 hours when Omeprazole is dissolved in saline and within 6 hours when dissolved in 5% Dextrose. The reconstituted solution should not be mixed or co-administered in the same infusion set with any other drug.

CONTRAINDICATION AND WARNING: There are no known contraindications to the use of Omeprazole. When gastric ulcer is suspected, the possibility of malignancy should be excluded before treatment with Omeprazole is instituted as treatment may alleviate symptoms and delay diagnosis.

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.

OVERDOSE: Symptoms were transient, and no serious clinical outcome has been reported with Omeprazole overdose. No specific antidote for Omeprazole overdose is known. Omeprazole is extensively bound with protein and is, therefore, not readily dialyzable. In the event of overdose, treatment should be symptomatic and supportive.

STORAGE CONDITION: Store in a cool (below 30°C) and dry place, protected from light.

HOW SUPPLIED: Seclo® 20 Capsule: Box containing 100's capsules in Alu-Alu blister pack. Seclo® 40 Capsule: Box containing 30's capsules in Alu-Alu blister pack. Seclo® DR 20 Tablet: Box containing 60's tablets in Alu-Alu blister pack. Seclo® 40 IV Injection: Box containing one vial of lyophilized Omeprazole 40 mg, one ampoule of water for injection BP 10 ml and one sterile disposable syringe (10 ml).

Manufactured by:

