

Seclo®

Omeprazole

Prescription Only Medicine

COMPOSITION

Seclo® 20 Capsule: Each delayed release capsule contains Omeprazole BP 20 mg as enteric coated pellets.

Seclo® 40 Capsule: Each delayed release capsule contains Omeprazole BP 40 mg as enteric coated pellets.

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 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 : Omeprazole should be taken before meal.

Disease	Dosage & 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.

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 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.

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 below 30°C. Protect from light and moisture. Keep out of children's reach.

HOW SUPPLIED

Seclo® 20 Capsule: Box containing 10 x 10's capsules in Alu-Alu blister pack.

Seclo® 40 Capsule: Box containing 5 x 6's capsules in Alu-Alu blister pack.

SQUARE