

# Seclo<sup>®</sup>

Omeprazole

## COMPOSITION

Seclo<sup>®</sup> 20 Capsule: Each delayed release capsule contains Omeprazole BP 20 mg as enteric coated granules.

Seclo<sup>®</sup> 40 Capsule: Each delayed release capsule contains Omeprazole BP 40 mg as enteric coated granules.

Seclo<sup>®</sup> DR 20 Tablet: Each delayed release tablet contains Omeprazole Magnesium INN equivalent to Omeprazole 20 mg.

## 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 oesophagitis. 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

Benign gastric and duodenal ulcers including those complicating NSAID therapy, heartburn and other symptoms associated with GERD, erosive oesophagitis, pathological hypersecretory conditions such as the Zollinger-Ellison syndrome and to eradicate *H. pylori* in combination with Clarithromycin & Amoxicillin.

## DOSAGE AND ADMINISTRATION

Benign gastric and duodenal ulcers including those complicating NSAID therapy: 20 mg once daily for 4 weeks in duodenal ulceration or 40 mg once a day for 4-8 weeks in gastric ulceration. Sometimes an additional 4 weeks of therapy is required.

Heartburn and other symptoms associated with GERD: 20 mg daily for up to 4 weeks. Erosive oesophagitis: 20 mg daily for 4-8 weeks. If there is recurrence of Erosive oesophagitis or GERD symptoms (e.g., Heartburn), an additional 4-8 weeks therapy may be considered. Maintenance of Healing of Erosive Oesophagitis: 20 mg daily.

Pathological hypersecretory conditions such as the Zollinger-Ellison syndrome: Adult oral starting dose is 60 mg once a day. Doses should be adjusted to individual patient needs and should continue for as long as clinically indicated. Doses up to 120 mg t.i.d. may be administered. Daily doses of greater than 80 mg should be administered in divided doses. Patients with Zollinger-Ellison syndrome may be treated with Omeprazole delayed release preparations continuously for more than 5 years.

Eradication of *H. pylori* in combination with Clarithromycin & Amoxicillin: 20 mg with Clarithromycin 500 mg & Amoxicillin 1000 mg twice daily for 7-14 days.

Pediatric Patients

For the treatment of GERD or other acid-related disorders, the recommended dose for pediatric patients 2 years of age and older is as follows:

<b>Patient Weight</b>	<b>Omeprazole Dose</b>
<20 kg	10 mg
≥20 kg	20 mg

### **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**

Omeprazole should be used during pregnancy only if the potential benefit to the pregnant woman justifies the potential risk to the fetus. Because omeprazole is excreted in human milk, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

### **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 the treatment. There is no evidence of interaction with theophylline, propranolol or antacids.

### **STORAGE**

Store in a cool and dry place, protected from light and moisture.

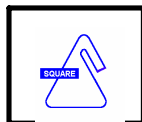
### **HOW SUPPLIED**

Seclo<sup>®</sup> 20 Capsule: Each box contains 16 x 6 capsules in strip pack.

Seclo<sup>®</sup> 40 Capsule: Each box contains 5 x 6 capsules in Alu-Alu blister pack.

Seclo<sup>®</sup> DR 20 Tablet: Each box contains 6 x 10 tablets in Alu-Alu blister pack.

Manufactured by:



**SQUARE**  
**PHARMACEUTICALS LTD.**  
**BANGLADESH**

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