

## Composition

**Onepro 20 Tablet:** Each delayed release tablet contains Esomeprazole Magnesium Trihydrate USP equivalent to Esomeprazole 20 mg.  
**Onepro 40 Tablet:** Each delayed release tablet contains Esomeprazole Magnesium Trihydrate USP equivalent to Esomeprazole 40 mg.  
**Onepro 20 Capsule:** Each capsule contains Esomeprazole Magnesium Trihydrate USP equivalent to Esomeprazole 20 mg as Enteric coated pellets.  
**Onepro 40 Capsule:** Each capsule contains Esomeprazole Magnesium Trihydrate USP equivalent to Esomeprazole 40 mg as Enteric coated pellets.  
**Onepro 40 IV Injection:** Each vial contains Esomeprazole 40 mg (as lyophilized powder of Esomeprazole Sodium USP) and each ampoule contains 5 ml 0.9% Sodium Chloride BP injection.

## Pharmacology

Esomeprazole is a proton pump inhibitor that suppresses gastric acid secretion by specific inhibition of the H<sup>+</sup>/K<sup>+</sup>ATPase in the gastric parietal cell. By acting specifically on the proton pump, Esomeprazole blocks the final step in acid production, thus reducing gastric acidity.

## Indication

- Treatment of Gastroesophageal Reflux Disease (GERD)
  - Healing of Erosive Esophagitis
  - Maintenance of Healing of Erosive Esophagitis
  - Symptomatic Gastroesophageal Reflux Disease
- *H. pylori* Eradication to Reduce the Risk of Duodenal Ulcer Recurrence
- Zollinger-Ellison Syndrome
- Acid Related Dyspepsia
- Duodenal and Gastric Ulcer

## Dose and Administration

a) *Route of administration:* Oral

**Tablet/Capsule:** The recommended adult & children dosages are outlined in the table below. Esomeprazole delayed release tablet/capsule should be swallowed whole and taken at least one hour before eating.

**Recommended Adult & Children Dosage Schedule of Esomeprazole**

Indication	Patient age	Recommended Dosage	Duration
Healing of Erosive Esophagitis	Adult: ≥ 18 Years of age	20 mg or 40 mg once daily	4 to 8 weeks
	Adolescent: 12 years to 17 years of age		
Maintenance of Healing of EE	Adult: ≥ 18 Years of age	20 mg once daily	Up to 6 months
Treatment of Symptomatic GERD	Adult: ≥ 18 Years of age	20 mg once daily	Up to 4 weeks
	Adolescent: 12 years to 17 years of age		
Risk Reduction of NSAID-Associated Gastric Ulcer	Adult: ≥ 18 Years of age	20 mg or 40 mg once daily	Up to 6 months
<i>H. pylori</i> Eradication to Reduce the Risk of Duodenal Ulcer Recurrence (Triple Therapy)		Esomeprazole 40 mg once daily Amoxicillin 1000 mg twice daily Clarithromycin 500 mg twice daily	10 Days
Pathological Hypersecretory Conditions Including Zollinger-Ellison Syndrome		Starting dosage is 40 mg twice daily; The dose can be increased up to a maximum of 240 mg/day according to the patient's needs.	As long as clinically indicated

\*The majority of patients are healed within 4 to 8 weeks. For patients who do not heal after 4-8 weeks, an additional 4-8 weeks of treatment may be considered.

\*\*If symptoms do not resolve completely after 4 weeks, an additional 4 weeks of treatment may be considered.

b) *Route of administration:* Parenteral

**IV Injection:** The recommended adult dosages are outlined in the table below.

Indication	Patient age	Dose	Application time
GERD with Erosive Esophagitis	Adult Patients (≥18 Years)	20 or 40 mg	Once daily for 10 days (IV Injection: >3 Minutes)

Method of Administration: Solution for injection is prepared by adding 5 ml of 0.9% Sodium Chloride for intravenous injection into the vial containing the dry powder. The reconstituted solution for injection is clear and colorless to very slightly yellow. IV injection must be administered intravenously over a period of at least 3 minutes. Prepared solution must be used within 12 hours of preparation and can be exposed to normal indoor lighting at a maximum of 30°C.

## Contra-indication

Esomeprazole is contraindicated in patients with known hypersensitivity to any component of the formulation or to substituted Benzimidazoles.

## Warning & Precaution

Symptomatic response to therapy with Esomeprazole does not preclude the presence of gastric malignancy. Atrophic gastritis has been noted occasionally in gastric corpus biopsies from patients treated long-term with omeprazole, of which Esomeprazole is an enantiomer.

## Side effects

a) *Common:* Esomeprazole was well tolerated in both short- and long-term clinical trials. The most frequently occurring adverse events (≥1%) are headache and diarrhoea.

b) *Rare:* Nausea, flatulence, abdominal pain, constipation and dry mouth may occur sometime.

## Use in Pregnancy and Lactation

*In Pregnancy:* Pregnancy Category B. This drug should be used during pregnancy only if clearly needed.

*In Lactation:* The excretion of Esomeprazole in milk has not been studied. As Esomeprazole is likely to be 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.

## Use in Children & Adolescents

See the dose and administration.

## Drug Interaction

a) *With Medicine:* Drug interaction studies have shown that Esomeprazole does not have any clinically significant interactions with Phenytoin, Warfarin, Quinidine, Clarithromycin or Amoxicillin. Esomeprazole inhibits gastric acid secretion. Therefore, Esomeprazole may interfere with the absorption of drugs where gastric pH is an important determinant of bioavailability (eg, Ketoconazole, Iron salts and Digoxin). Coadministration of oral contraceptives, Diazepam, Phenytoin or Quinidine did not seem to change the pharmacokinetic profile of Esomeprazole.

b) *With food & others:* May reduced absorption due to presence of food.

## Overdose

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

## Storage

Store below 30°C. Protect from light & moisture. Keep all medicines out of reach of children.

## Packing

**Onepro 20 Tablet:** Each box contains 60 (6x10's) tablets in Alu-Alu blister Pack.

**Onepro 40 Tablet:** Each box contains 30 (3x10's) tablets in Alu-Alu blister Pack.

**Onepro 20 Capsule:** Each box contains 60 (6x10's) Capsules in Alu-Alu blister Pack.

**Onepro 40 Capsule:** Each box contains 30 (3x10's) Capsules in Alu-Alu blister Pack.

**Onepro 40 IV Injection:** Each box contains 1 Vial of lyophilized powder of Esomeprazole USP 40 mg, 1 ampoule of 5 ml 0.9% Sodium Chloride BP injection, 1 disposable syringe (5 ml) and alcohol pad.

Manufactured by

**ONE PHARMA LTD.**

C-23-24, BSCIC I/A

Bogura, Bangladesh

Onepro 40 IV Injection is Manufactured by  
**Apex Pharma Ltd.**

Shafipur, Kaliakair, Gazipur, Bangladesh.

for **ONE PHARMA LTD.**

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