

### Composition

**Aspra-20 Capsule:** Each capsule contains Omeprazole USP 20 mg as enteric coated 22.5% Omeprazole in pellets.

**Aspra-40 Capsule:** Each capsule contains Omeprazole USP 40 mg as enteric coated 22.5% Omeprazole in pellets.

### Pharmacology

Aspra (Omeprazole) is a substituted benzimidazole that suppresses gastric acid secretion by specific inhibition of the gastric acid proton pump (H<sup>+</sup>/K<sup>+</sup> ATPase enzyme system) at the secretory surface of the gastric parietal cell. It blocks the final step of acid production. After oral administration, the onset of the antisecretory effect of Omeprazole occurs within one hour, with the maximum effect occurring within two hours and the duration of inhibition lasts up to 72 hours. The antisecretory effect lasts far longer than would be expected from the very short (less than one hour) plasma half-life, apparently due to prolonged binding to the parietal H<sup>+</sup>/K<sup>+</sup> ATPase enzyme. Following absorption, Omeprazole is almost completely metabolized and rapidly eliminated mostly through urine.

### Indication

Aspra is indicated in the treatment of heartburn, any symptoms of GERD, erosive esophagitis (both curative and maintenance therapy), duodenal ulcer, gastric ulcers, reduction of risk of upper GI bleeding in critically ill patients.

### Dosage & Administration

Aspra should be taken before meal. No dose adjustment is necessary for patients with renal impairment, hepatic dysfunction or for the elderly.

**Duodenal Ulcer:** The recommended adult oral dose is 20 mg once daily. Most patients heal within four weeks. Some patients may require an additional four weeks of therapy.

**Gastric Ulcer:** The recommended adult oral dose is 40 mg once a day for 4-8 weeks.

**Gastroesophageal Reflux Disease (GERD):** The recommended adult oral dose is 20 mg daily for up to 4 weeks.

**Erosive esophagitis:** The recommended adult oral dose is 20 mg daily for 4 to 8 weeks.

**Zollinger-Ellison syndrome:** The recommended 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. have been administered. Daily dosages of greater than 80 mg should be administered in divided doses.

### Contraindication

Omeprazole is contraindicated in patients with known hypersensitivity to any components of the formulation.

### Precaution

Symptomatic response to therapy with Omeprazole does not preclude the presence of gastric malignancy.

### Side Effect

Omeprazole is well tolerated and adverse reactions have generally been mild and reversible. Side-effects may include headache, diarrhoea, constipation, abdominal pain, nausea/vomiting and flatulence, dizziness, paraesthesia, somnolence, insomnia and vertigo, increased liver enzymes, rash, dermatitis and/or pruritus, urticaria, Malaise. Others include hypersensitivity reactions e.g. angioedema, fever, bronchospasm, interstitial nephritis and anaphylactic shock.

### Use in Pregnancy & Lactation

**Pregnancy:** There are no adequate and well-controlled studies on the use of Omeprazole in pregnant women. Therapeutic doses during pregnancy are unlikely to pose a substantial teratogenic risk. Omeprazole should be used during pregnancy only if the potential benefit to pregnant women justifies the potential risk to the fetus.

**Lactation:** Omeprazole is excreted in human milk. Thus, a decision should be taken to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

### Overdosage

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

Keep away from light & moisture and store below 30° C. Keep out of the reach of children.

### Packaging

**Aspra-20 Capsule:** Each box contains 6x10's capsules in blister pack.

**Aspra-40 Capsule:** Each box contains 3x10's capsules in blister pack.