

## NORMA-20 CAPSULES

Generic name	Omeprazole
Drug Category	Proton Pump Inhibitor
Presentation	Each capsule contains Omeprazole BP 20 mg (As enteric coated granules) Available as 15 Capsules x 15 Strips

### MECHANISM OF ACTION

Norma-20 (Omeprazole) capsule is a proton pump inhibitors that decrease the amount of acid in the stomach.  $H^+K^+ATPase$ , an enzyme system (proton pump) is found at the secretory surface of parietal cells. The protons pump release hydrochloric acid in the stomach. Omeprazole binds to this proton pump, thereby inhibits the final transport of hydrogen ions (Via exchange of potassium ion) into the gastric lumen, blocks the secretion of acid into the stomach. This quickly relieves pain and promotes healing of ulcer. Thus, it inhibits the gastric acid secretion (up to 100%) and also the activity of pepsin.

### INDICATION

- Gastroesophageal Reflux Disease [GERD) (Prophylaxis and Treatment)
- Heartburn and other symptoms associated with GERD
- Erosive oesophagitis (Treatment)
- Hypersecretary condition (Treatment)
- Zollinger-Ellison Syndrome, (Treatment) a Hypersecretary condition
- Ulcer Peptic [Duodenal, Gastric] (Treatment)
- Ulcer Peptic NSAID Induced (Treatment)
- Treatment of *Helicobacter pylori* (In combination with antibiotics as dual or triple therapy)

### PHARMACOKINETICS

Absorption: Rapid

Distribution: Distributed in tissue, preferentially, gastric parietal cells

Protein binding: Very high 95% bound to albumin and □ 1-acid glycoprotein

Biotransformation: Hepatic extensive

Half-life: Normal Hepatic function: 30 minutes to 1 hours

Onset of action: Within 1 hour

Time to peak effect: 2 hours

Duration of action: Upto 72 hours or more

Elimination: Renal 72-80% and Fecal 78-23%

In dialysis: not readily dialyzed because of extensive protein binding

## **DOSAGE**

### **FOR DUODENAL ULCER OR GERD**

The usual dose of NORMA-20 is 20mg once daily for 4-8 weeks or as directed by Physician. Occasionally, dosages up to 40 mg daily may be necessary in patients who have been poorly responsive to therapy with H<sub>2</sub>-receptor antagonists.

Norma-20 is taken before meal (preferentially the morning meal), or may be taken with food or an empty stomach.

### **For triple therapy**

Triple Therapy (NORMA-20/clarithromycin/amoxicillin): The recommended adult oral regimen is NORMA- 20 Plus clarithromycin 500 mg plus amoxicillin 1000 mg each given twice daily for 10 days. In patients with an ulcer present at the time of initiation of therapy, an additional 18 days of NORMA-20 once daily is recommended for ulcer healing and symptom relief.

### **FOR GASTRIC ULCER**

For the short-term treatment of active benign gastric ulcer, the usual adult dosage of omeprazole is 40 mg once daily for 4—8 weeks.

### **FOR PATHOLOGIC GI HYPERSECRETORY CONDITIONS**

For the treatment of pathologic GI hypersecretory conditions (e.g., Zollinger-Ellison syndrome, multiple endocrine adenomas, systemic mastocytosis), dosages of omeprazole should be individualized according to patient response and tolerance. The usual initial adult dosage is 60 mg once daily. Subsequent omeprazole dosage should be adjusted as tolerated and necessary to adequately suppress gastric acid secretion, and therapy continued as long as clinically necessary. Daily dosages exceeding 80 mg should be administered in divided doses.

Omeprazole has been given continuously for more than 5 years in some patients with Zollinger-Ellison syndrome.

### **DOSAGE IN RENAL IMPAIRMENT**

Although pharmacokinetics may be altered in patients with renal impairment, dosage adjustment does not appear necessary in patients with such impairment.

## **SIDE EFFECT**

The usual side-effects are Headache, Diarrhoea, abdominal pain, nausea, vomiting, constipation and flatulence.

## **PRECAUTION**

**NORMA-20** is not recommended in pregnancy and breast feeding unless the benefit outweighs possible risk. Omeprazole should be used in caution in patients with hepatic impairment and dosage adjusted accordingly.

*Pregnancy:* Well control study have not been done

*Breast-feeding:* Not know whether Omeprazole is distributed in human milk.

## **DRUG INTERACTION**

Omeprazole may interfere with absorption of drugs where gastric pH is an important determinant of their bioavailability (e.g., ketoconazole, ampicillin esters, and iron salts). Antacids were used concomitantly with the administration of NORMA-20.