



# Nexum<sup>®</sup>

Esomeprazole  
**Antiulcerants**

## COMPOSITION

Nexum<sup>®</sup> 20 tablet: Each enteric coated tablet contains Esomeprazole INN 20 mg as Esomeprazole Magnesium Trihydrate.

Nexum<sup>®</sup> 40 tablet: Each enteric coated tablet contains Esomeprazole INN 40 mg as Esomeprazole Magnesium Trihydrate.

## PHARMACOLOGY

Nexum<sup>®</sup> (Esomeprazole) is indicated for the relief of heartburn and other symptoms associated with gastroesophageal reflux disease (GERD) and for the healing of erosive esophagitis, a potentially serious condition associated with GERD. The FDA approved Esomeprazole for maintenance of healing of erosive esophagitis and in combination with amoxicillin and clarithromycin, for the eradication of *Helicobacter pylori* infection in patients with duodenal ulcer disease.

## DOSAGE AND ADMINISTRATION

Recommended Adult Dosage Schedule of Nexum<sup>®</sup>

| Indication  | Dose           | Frequency                    |
|---|----------------|------------------------------|
| Gastroesophageal Reflux Disease (GERD)  |                |                              |
| Healing of Erosive Esophagitis  | 20 mg or 40 mg | Once daily for 4 to 8 weeks* |
| Maintenance of Healing of Erosive Esophagitis                                       | 20 mg          | Once Daily **                |
| Symptomatic Gastroesophageal Reflux   | 20 mg          | Once daily for 4 weeks ***   |
| <b><i>H. pylori</i> Eradication to reduce the Risk of Duodenal Ulcer Recurrence</b> |                |                              |
| <b>Triple Therapy :</b>   |                |                              |
| Nexum <sup>®</sup>  | 40 mg          | Once daily for 10 Days       |
| Amoxicillin   | 1000 mg        | Twice daily for 10 Days      |
| Clarithromycin  | 500 mg         | Twice daily for 10 Days      |

\* 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 treatment may be considered.

\*\* Controlled studies did not extend beyond six months.

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

Nexum<sup>®</sup> is supplied as tablets which should be swallowed whole with liquid.

## CONTRAINDICATION AND PRECAUTION

Esomeprazole is contraindicated in those patients who have known hypersensitivity to any component of the formulation.

Exclude the possibility of malignancy when gastric ulcer is suspected and before treatment for dyspepsia. When using in combination with antibiotic,

refer to the prescribing information of the respective antibiotics.

**SIDE EFFECT**

Side effects reported with Esomeprazole include the following:

- Headache
- Diarrhoea
- Abdominal pain

**USE IN PAEDIATRIC PATIENT**

Safety and effectiveness have not yet been established in paediatric patients.

**SPECIAL POPULATION**

*Geriatric* : No dosage adjustment is necessary.

*Renal Insufficiency* : No dosage adjustment is necessary.

*Hepatic Insufficiency* : No dosage adjustment is necessary in patients with mild to moderate liver impairment. For patients with severe liver impairment a dose of 20 mg of Nexum<sup>®</sup> should not be exceeded.

*Gender*: No dosage adjustment is necessary.

**DRUG INTERACTION**

Esomeprazole appears to be a selective inhibitor of the cytochrome P-450 mono-oxygenase system; there may be an effect on hepatic clearance, but there have been no reports to date of clinically relevant interactions. There is some uncertainty over the effect of Esomeprazole on the oral combined contraceptive pill. Further assessment is currently underway. Physiological changes similar to those found with omeprazole are likely to take place because of the reduction in gastric acid, which is likely to influence the bacterial colonization of the stomach and duodenum and also vitamin B12 absorption.

**STORAGE CONDITION**

Store at room temperature and protected from light. Keep all medicines out of reach of children.

**HOW SUPPLIED**

Nexum<sup>®</sup> 20 tablet : Box containing 3x10 tablets in Alu-Alu blister pack.

Nexum<sup>®</sup> 40 tablet : Box containing 3x10 tablets in Alu-Alu blister pack.

