Nexum®

Esomeprazole

COMPOSITION

Nexum® 20 Capsule: Each delayed release capsule contains enteric coated pellets of Esomeprazole Magnesium Trihydrate USP equivalent to Esomeprazole 20 mg.

Nexum® 40 Capsule: Each delayed release capsule contains enteric coated pellets of Esomeprazole Magnesium Trihydrate USP equivalent to Esomeprazole 40 mg.

Nexum® 40 IV Injection: Each vial contains Esomeprazole 40 mg (as lyophilized powder of Esomeprazole Sodium INN) and each ampoule contains 5 ml of 0.9% Sodium Chloride Injection BP.

INDICATION

Treatment of Gastroesophageal Reflux Disease (GERD)
Healing of erosive esophagitis
Maintenance of healing of erosive esophagitis
Symptomatic Gastroesophageal Reflux Disease (GERD)
Risk Reduction of NSAID-associated gastric ulcer
H. pylori eradication (Triple therapy)

DOSAGE & ADMINISTRATION

Tablet and capsule:
Recommended adult dosage schedule of Esomeprazole
Paediatric use (12 years and older)

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 GERD	20 mg	Once daily for 4 weeks ***
Risk Reduction of NSAID- associated gastric ulcer	20 mg or 40 mg	Once daily for up to 6 months**
***H. pylori* eradication (Triple therapy)**		
Esomeprazole	20 mg	Twice daily for 10 days
Amoxicillin	1000 mg	Twice daily for 10 days
Clarithromycin	500 mg	Twice daily for 10 days

Short term treatment of GERD: 20 mg or 40 mg once daily for up to 8 weeks
* 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.

Injection

Duodenal ulcer, gastric ulcer, gastrointestinal lesions refractory to H2 blockers, Zollinger-Ellison syndrome	40 mg per day intravenously
Reflux esophagitis	20-40 mg per day intravenously

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 should not be exceeded.
Gender: No dosage adjustment is necessary.

DIRECTION FOR USE OF IV INJECTION

Esomeprazole lyophilized powder and 0.9% Sodium Chloride Injection is for intravenous administration only and must not be given by any other route. Esomeprazole injection 40 mg should be given as a slow intravenous injection. The solution for IV injection is obtained by adding 5 ml 0.9% Sodium Chloride Injection to the vial containing powder. After reconstitution the injection should be given slowly over a period of at least 3 minutes. Use only freshly prepared solution. The reconstituted solution may be stored at room temperature (up to 30°C) for a maximum 12 hours. Half of the IV injection should be used when 20 mg to be administered.

DIRECTION FOR USE OF IV INFUSION

Esomeprazole IV 40 mg should be given as an intravenous infusion over a period of 10 to 30 minutes. Esomeprazole IV should be reconstituted with 5 ml of 0.9% Sodium Chloride Injection and further diluted (admixed) with 5% Dextrose Injection or 0.9% Sodium Chloride Injection or Lactated Ringer's Injection to a final volume of 50 ml. The reconstituted solution may be stored at room temperature (up to 30°C) for a maximum 12 hours prior to dilution. The admixed solution may be stored at room temperature (up to 30°C) and must be used within 12 hours when reconstituted with 0.9% Sodium Chloride Injection or Lactated Ringer's Injection and within 6 hours when reconstituted with 5% Dextrose Injection.

CONTRAINDICATION

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

PRECAUTION

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.

USE IN PREGNANCY AND LACTATION

US FDA Pregnancy Category – 'C'
This drug should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. 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.

SIDE EFFECT

Side effects reported with Esomeprazole include headache, diarrhea and abdominal pain.

DRUG INTERACTION

Esomeprazole appears to be a selective inhibitor of the cytochrome p450 monooxygenase 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

Store in a cool (below 30°C) and dry place, protected from light.

HOW SUPPLIED

Nexum® 20 Capsule: Each box contains 60's capsules in Alu-Alu blister pack.
Nexum® 40 Capsule: Each box contains 30's capsules in Alu-Alu blister pack.
Nexum® 40 IV Injection: Each box contains one vial of lyophilized Esomeprazole 40 mg, one ampoule of 5 ml 0.9% Sodium Chloride Injection and one sterile disposable syringe (5 ml).

Manufactured by

SQUARE
PHARMACEUTICALS LTD.
BANGLADESH