Nesotem®

Naproxen USP & Esomeprazole USP

COMPOSITION:

Nesotem ® 375 Tablet: Each enteric coated tablet contains Naproxen USP 375 mg (as Naproxen Sodium) & Esomeprazole USP 20 mg (as Esomeprazole Magnesium Trihydrate).

Nesotem ® 500 Tablet : Each enteric coated tablet contains Naproxen USP 500 mg (as Naproxen Sodium) & Esomeprazole USP 20 mg (as Esomeprazole Magnesium Trihydrate).

PHARMACOLOGY:

Naproxen is a NSAIDs with analgesic and antipyretic properties. The mechanism of action of naproxen is like that of other NSAIDs, related to prostaglandin synthetase inhibition.Esomeprazole is a proton pump inhibitor that suppresses gastric acid secretion by specific-inhibition of the H+/K+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:

Nesotem ® Tablet is indicated for the relief of signs and symptoms of osteoarthritis, rheumatoid arthritis and ankylosing spondylitis and to decrease the risk of developing gastric ulcers in patients at risk of developing NSAIDs associated gastric ulcers.

DOSE & ADMINISTRATION:

The dosage is one tablet twice daily of Nesotem ® 375 Tablet or Nesotem ® 500 Tablet. Nesotem ® Tablet is to be taken at least 30 minutes before meals.

CONTRA-INDICATION:

This combination is contraindicated in patients with known hypersensitivity to Naproxen, Esomeprazole Magnesium or to any of the excipients. This combination is contraindicated in patients who have experienced asthma, urticaria or allergic type reactions after taking aspirin or other NSAIDs. This combination is also contraindicated for the treatment of perioperative pain in the setting of coronary artery bypass graft (CABG) surgery and in patients in the late stages of pregnancy.

WARNING AND PRECAUTION:

* Serious and potentially fatal cardiovascular (CV) thrombotic events, myocardial infarction and stroke. Patients with known CV disease/risk factors may be at greater risk.
* Serious gastrointestinal (GI) adverse events, which can be fatal. The risk is greater in patients with a prior history of ulcer disease or GI bleeding and in patients at high risk for GI events, especially the elderly. Nesotem ® Tablet should be used with caution in these patients
* Treatment should be withdrawn when active and clinically significant bleeding from any source occurs.
* Elevated liver enzymes and rarely, severe hepatic reactions. Discontinue use immediately if abnormal liver enzymes persist or worsen. New onset or worsening of pre-existing hypertension. Blood pressure should be monitored closely during treatment with Nesotem ® Tablet.
* Congestive heart failure and edema. Nesotem ® Tablet should be used with caution in patients with fluid retention or heart failure
* Renal papillary necrosis and other renal injury with long-term use. Use Nesotem ® Tablet with caution in the elderly, those with impaired renal function, hypovolemia, salt depletion, heart failure, liver dysfunction, and those taking diuretics or ACE-inhibitors. Not recommended for patients with moderate or severe renal impsairment.
* Anaphylactoid reactions. Do not use Nesotem ® Tablet in patients with the aspirin triad.
* Discontinue Nesotem ® Tablet at first appearance of skin rash or any other sign of hypersensitivity

SIDE EFFECTS:

Nausea, abdominal pain, dyspepsia, constipation, headache, dizziness, raised liver enzymes, menstrual disorders, allergic reactions (including pruritus, rash, urticaria and angioedema), hepatitis and cholestatic jaundice, peripheral neuropathy and Stevens-Johnson syndrome reported. On prolonged use hypokalaemia, oedema and hair loss reported.

USE IN PREGNANCY & LACTATION:

Use in pregnancy: There are no adequate and well-controlled studies in pregnant women. This combination should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Use in nursing mothers: This combination should not be used in nursing mothers.

USE IN CHILDREN & ADOLESCENTS:

The safety and efficacy of Naproxen & Esomeprazole combination have not been established in children younger than 18 years.

DRUG INTERACTION:

Several studies have shown no interaction between the two components Naproxen and Esomeprazole. NSAIDs may diminish the antihypertensive effect of ACE- inhibitors. Probenecid increases Naproxen anion plasma levels and extends its plasma half-life significantly. Co-administration of oral contraceptives, diazepam, phenytoin, or quinidine does not seem to change the pharmacokinetic profile of Esomeprazole.

OVERDOSE:

Naproxen*:* Significant naproxen overdosage may be characterized by lethargy, drowsiness, epigastric pain, abdominal discomfort, heartburn, indigestion, nausea, transient alterations in liver function, hypoprothrombinemia, renal dysfunction, metabolic acidosis, apnea, vomiting etc.

Esomeprazole*:* The major signs of acute toxicity were reduced motor activity, changes in respiratory frequency, tremor and intermittent clonic convulsions etc.

STORAGE:

Store in a dry and cool place below 30^0 C temperature and keep away from light and moisture. Keep out of reach of children.

PACKING:

Nesotem ® 375 Tablet: Each box contains 5x4's tablets in Alu-Alu blister pack.

Nesotem ® 500 Tablet: Each box contains 5x10's tablets in Alu-Alu blister pack.

Manufactured by

Team Pharmaceuticals Ltd.

B 75-79, BSCIC, Rajshahi, Bangladesh

IST-0028