

Emaprox

(Naproxen & Esomeprazole)

Presentation

Emaprox 375 Tablet: Each tablet contains delayed release Naproxen USP 375 mg and immediate release Esomeprazole Magnesium Trihydrate USP equivalent to Esomeprazole 20 mg.

Emaprox 500 Tablet: Each tablet contains delayed release Naproxen USP 500 mg and immediate release Esomeprazole Magnesium Trihydrate USP equivalent to Esomeprazole 20 mg.

Indication

Emaprox tablet is indicated for the conditions-

- Relief of signs and symptoms of osteoarthritis
- Rheumatoid arthritis
- Ankylosing spondylitis and
- Patients at risk of developing NSAIDs-associated gastric ulcer

Dosage and Administration

Emaprox 375 (Naproxen 375 mg and Esomeprazole 20 mg): One tablet twice daily

Emaprox 500 (Naproxen 500 mg and Esomeprazole 20 mg): One tablet twice daily depending on the requirements or as directed by the physicians.

Emaprox is to be taken at least 30 minutes before meals.

Geriatric Patients: Studies indicate that total plasma concentration of naproxen is unchanged; the unbound plasma fraction of naproxen is increased in the elderly. Caution is advised when high doses are required and some adjustment of dosage may be required in elderly patients.

Children: Dosage in children less than 18 years has not been established

Hepatic Insufficiency: This combination is not recommended for use in patients with severe hepatic impairment because Esomeprazole dose should not exceed 20 mg daily in these patients.

Renal Insufficiency: In case of patients with advanced renal disease & creatinine clearance < 30 mL/min, this combination is not recommended.

Side Effect

Generally the combination of Naproxen and Esomeprazole is well tolerated. The most common adverse reactions in clinical trials are erosive gastritis, dyspepsia, gastritis, diarrhea, gastric ulcer, upper abdominal pain, nausea etc.

Contraindication

Known hypersensitivity to any component of Naproxen and Esomeprazole or substituted benzimidazoles. History of asthma, urticaria or other allergic reactions after taking aspirin or other NSAIDs. Contraindicated during the peri-operative period in the setting of coronary artery bypass graft (CABG) surgery and late pregnancy.

Precaution

Patients with known CV disease/risk factors may be at greater risk. combination of Naproxen and Esomeprazole should be used with caution in patients with fluid retention or heart failure.

Pregnancy & Lactation

Pregnancy: Esomeprazole is safe in pregnancy but Naproxen is pregnancy category C, so this combination should be used in pregnancy only if the potential benefit justifies the potential risk to the fetus. **Lactation:** Naproxen & Esomeprazole are 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

Drug interaction

Some products that may interact with this drug include: aliskiren, ACE, angiotensin II receptor blockers, corticosteroids, lithium, methotrexate, pemetrexed, probenecid, rifampin. Emaprox may increase the risk of bleeding when taken with anti-platelet and blood thinners.

Overdose

Overdose of Naproxen: Significant naproxen overdose may be characterized by lethargy, drowsiness, epigastric pain, abdominal discomfort, heartburn, indigestion, nausea, transient alterations in liver function, renal dysfunction, metabolic acidosis, apnea, vomiting etc. Overdose of Esomeprazole: The major signs of acute toxicity were reduced motor activity, changes in respiratory frequency, tremor and intermittent clonic convulsions etc.

Commercial Packaging:

Emaprox 375 Tablet: Each box contains 3 x 10 tablets in blister strips.

Emaprox 500 Tablet: Each box contains 3 x 10 tablets in blister strips.

Manufactured by

GLOBE PHARMACEUTICALS LTD.
BANGLADESH.