

Composition : Naproxen + Esomeprazole; (375mg+20mg) & (500mg+20mg) Tablet.

Indications : This is indicated for the relief of signs and symptoms of osteoarthritis, rheumatoid arthritis and ankylosing spondylitis, dysmenorrhoea and to decrease the risk of developing gastric ulcers in patients at risk of developing NSAID-associated gastric ulcers.

Dosage and administration : Rheumatoid Arthritis, Osteoarthritis and Ankylosing Spondylitis : The dosage is one tablet twice daily of 375mg naproxen and 20mg of esomeprazole or 500mg naproxen and 20mg of esomeprazole. The tablets are to be swallowed whole with liquid. This drug is to be taken at least 30 minutes before meals.

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

Patients with Moderate to Severe Renal Impairment : Naproxen-containing products are not recommended for use in patients with moderate to severe or severe renal impairment (creatinine clearance < 30 mL/min). **Hepatic Insufficiency :** Monitor patients with mild to moderate hepatic impairment closely and consider a possible dose reduction based on the naproxen component of this drug. It should be avoided in patients with severe hepatic impairment.

Paediatric Patients : The safety and efficacy of this drug in children younger than 18 years has not been established. Or, as directed by the registered physician.

Contraindication : Known hypersensitivity to any component of this tablet or substituted

Napsec Tablet

benzimidazoles. History of asthma, urticaria, or other allergic-type reactions after taking aspirine or other NSAIDs. Use (CABG) surgery. Late pregnancy.

Side effects : In general, this tablet is well tolerated. The most common adverse reactions in clinical trials erosive gastritis, dyspepsia, gastritis, diarrhea, gastric ulcer, upper abdominal pain, nausea etc.

Precautions : Patients with known CV diseases/risk factors may be at greater risk. This tablet should be used with caution in patients with fluid retention or heart failure.

Pregnancy and lactation : Pregnancy Category C. In late pregnancy, it should be avoided because it may cause premature closure of ductus arteriosus. Lactation : Naproxen is distributed in breast milk; avoid use because of prostaglandin inhibition effects in newborn.

Drug interactions : Concomitant use of NSAIDs may reduce the antihypertensive effect of ACE inhibitors, diuretics and beta-blockers. Concomitant use of this tablet and warfarin may result in increased risk of bleeding complications. Esomeprazole inhibits gastric acid secretion and may interfere with the absorption of drugs where gastric pH is an important determinant of bioavailability.

Packing :

Napsec-375 : 3x10's tablets.

Napsec-500 : 3x10's tablets.