

Neso[®]

Naproxen BP & Esomeprazole USP

Composition:

Neso[®] Tablet (375 mg/20 mg): Each enteric coated tablet contains Naproxen BP 375 mg & Esomeprazole Magnesium Trihydrate USP equivalent to Esomeprazole 20 mg.

Neso[®] Tablet (500 mg/20 mg): Each enteric coated tablet contains Naproxen BP 500 mg & Esomeprazole Magnesium Trihydrate USP equivalent to Esomeprazole 20 mg.

Pharmacology:

Naproxen is a NSAID 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.

Indications:

Neso[®] 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 NSAID-associated gastric ulcers.

Dosage and administration:

The dosage is one tablet twice daily of **Neso[®]** 375 mg naproxen and 20 mg of esomeprazole or 500 mg naproxen and 20 mg of esomeprazole. **Neso[®]** is to be taken at least 30 minutes before meals.

Contraindications:

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.

Side effects:

The adverse effects reported with this combination may include gastrointestinal disorders like dyspepsia, diarrhea, nausea, flatulence, abdominal pain etc.

Use in special groups:

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

Geriatric use: Caution is advised when high doses are required and some adjustment of dosage may be required in elderly patients.

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

Renal Insufficiency: Naproxen-containing products are not recommended for use in patients with advanced renal disease. (Creatinine Clearance 30 ml/ min.)

Drug interactions

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.

Storage:

- Store below 30°C, protect from light.
- Keep out of the reach of children

Packing:

Neso[®] Tablet (375 mg/20 mg): Each box contains 50's tablets in alu-alu blister pack.

Neso[®] Tablet (500 mg/20 mg): Each box contains 50's tablets in alu-alu blister pack.



Manufactured by:

ARISTOPHARMA LTD.
Shampur-Kadamtali I/A, Dhaka-Bangladesh

20002364/02