

Xenap Plus

Naproxen BP & Esomeprazole USP

Description :

Xenap plus contains two active ingredients Naproxen & Esomeprazole. Naproxen is a nonsteroidal anti-inflammatory drug that works by reducing substances in the body that cause pain, inflammation and fever. Esomeprazole is a proton pump inhibitor that inhibits excess acid secretion in the stomach.

Composition:

Xenap Plus 375 tablet: Each enteric coated tablet contains Naproxen Sodium BP equivalent to Naproxen 375 mg and Esomeprazole Magnesium Trihydrate USP equivalent to Esomeprazole 20 mg.

Xenap Plus 500 tablet: Each enteric coated tablet contains Naproxen Sodium BP equivalent to Naproxen 500 mg and Esomeprazole Magnesium Trihydrate USP equivalent to Esomeprazole 20 mg.

Indication:

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:

Osteoarthritis, rheumatoid arthritis and ankylosing spondylitis: One Xenap Plus 375 or Xenap Plus 500 tablet twice daily. Do not split, chew, crush, or dissolve the tablet. The tablet is to be taken at least 30 minutes before meals.

Elderly 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 in elderly patients.

Patients with renal impairment Naproxen containing products are not recommended for use in patients with moderate to severe renal impairment (creatinine clearance <30ml/min).

Children: Use in children less than 18 years has not been established yet.

Side effects :

In general, Xenap Plus is well tolerated. Most common side effects are seen with this combination are erosive gastritis, dyspepsia, diarrhea, gastric ulcer, upper abdominal pain, nausea etc.

Contraindication:

This combination is contraindicated in patients with known hypersensitivity to Naproxen, Esomeprazole or to any of the excipients. This is also contraindicated in patients who have history of asthma, urticaria, or other 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.

Drug interaction:

Concomitant use of NSAIDs may reduce the antihypertensive effect of ACE inhibitors, diuretics, and beta-blockers. Concomitant use of Xenap plus 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 (eg. Ketoconazole, iron salts and Digoxin).

Precaution:

Patients with known cardiovascular disease/risk factors may be at greater risk. Xenap plus should be used with caution in patients with fluid retention and heart failure.

Use in pregnancy and lactation:

Pregnancy category C. In late pregnancy, as with other NSAIDs, Naproxen should be avoided. Xenap plus should not be used in nursing mothers due to the Naproxen component.

Storage:

Store in a cool and dry place. Protect from light and moisture. Keep out of reach of children.

How supplied:

Xenap Plus 375 Tablet : Each box contains 3 x 10 tablets in alu-alu blister pack.

Xenap Plus 500 Tablet : Each box contains 5 x 6 tablets in alu-alu blister pack.

Manufactured by:

