Naprox® Plus

Naproxen Delayed Release & Esomeprazole Immediate Release tablet

DESCRIPTION

Naprox® Plus is the preparation of Naproxen & Esomeprazole. **Naprox® Plus** has been developed as a sequential-delivery tablet formulation combining an immediate release esomeprazole magnesium layer and an enteric coated delayed-release naproxen core. As a result, esomeprazole is released in the stomach prior to the dissolution of naproxen in the small intestine. The enteric coating prevents naproxen release at pH levels below 5.0 providing protection against possible local gastric toxicity of naproxen. Naproxen is a NSAID with analgesic and antipyretic properties. The mechanism of action of the naproxen anion, like that of other NSAIDs, is not completely understood but may be related to prostaglandin synthetase inhibition. Esomeprazole is a weak base and is concentrated and converted to the active form in the highly acidic environment of the secretory canaliculi of the parietal cell, where it inhibits the enzyme H^+- K^+ ATPase (the acid pump) and inhibits both basal and stimulated acid secretion.

INDICATIONS

Naprox® Plus is indicated for patients with an increased risk of gastrointestinal ulceration, who require NSAID therapy for symptomatic management of rheumatoid arthritis, ankylosing spondylitis and osteoarthritis with an inflammatory component and in whom lower doses of naproxen or other NSAIDs have proven insufficient. If a total daily dose of 1 g of naproxen is not required, **Naprox® Plus** should not be used.

DOSAGE AND ADMINISTRATION

The dose is 1 tablet twice daily. Controlled studies assessing the efficacy and safety of **Naprox® Plus** does not extend beyond 6 months of treatment. **Naprox® Plus** must be swallowed whole with water, and not split, chewed or crushed. It is recommended that **Naprox® Plus** is taken at least 30 minutes prior to food intake.

CONTRAINDICATIONS

- In patients who are hypersensitive to naproxen or naproxen sodium or in whom acetylsalicylic acid (aspirin) or other non-steroidal anti-inflammatory/analgesic agents induce allergic manifestations, e.g. asthma, nasal polyps, rhinitis and urticaria. Severe anaphylactic-like reactions to naproxen have been reported in such patients
- In patients with active, or a history of peptic or gastrointestinal ulceration, chronic dyspepsia or active gastrointestinal bleeding or perforation, related to previous NSAID therapy
- In patients with active, or history of recurrent peptic ulcer/haemorrhage (two or more distinct episodes of proven ulceration or bleeding) unrelated to previous NSAID therapy
- In patients 18 years of age or less since safety in this age group has not been established. History of asthma, urticaria or allergic-type reactions induced by administration of aspirin or other NSAIDs
- Third trimester of pregnancy
- Severe hepatic impairment (e.g. Childs-Pugh C)
- Severe heart failure
- Severe renal failure
- Cerebrovascular bleeding or other bleeding disorders

USE IN PREGNANCY AND LACTATION

Pregnancy category C. NSAIDs should not be used during the first two trimesters of pregnancy unless the potential benefit to the patient outweighs the potential risk to the foetus.

Naproxen is excreted in human milk at levels approximately 1% of plasma concentrations. It is not known if esomeprazole or its metabolites appear in human breast milk. No studies in lactating women have been performed. Therefore naproxen esomeprazole combination should not be used during breastfeeding.

SIDE EFFECTS

Naproxen esomeprazole combination contains both naproxen and esomeprazole and the same pattern of undesirable effects as reported for both of these individual active substances may occur. Gastrointestinal undesirable effects such as dyspepsia, stomach pain, nausea and vomiting are the most commonly reported undesirable effects in patients treated with naproxen alone. Naproxen esomeprazole combination has been developed with esomeprazole to decrease the incidence of gastrointestinal side effects from naproxen and has been shown to significantly decrease the occurrence of gastric ulcers and NSAID associated upper gastrointestinal adverse events compared to naproxen alone.

PRECAUTIONS

Special precautions should be taken for the patients who have active GI bleeding disorders, severe hepatic impairment, severe renal impairment, cardiovascular bleeding disorders & etc.

PHARMACEUTICAL PRECAUTION

Store in a cool (below 25 ^{o}C temperature) place. Keep away from light & wet place. Keep out of reach of children.

PACKAGING

Naprox® Plus 375 tablet: Box containing 5 strips of 6 tablets each. Each tablet contains Naproxen USP 375 mg and Esomeprazole Magnesium USP equivalent to Esomeprazole 20 mg.

Naprox® Plus 500 tablet: Box containing 6 strips of 6 tablets each. Each tablet contains Naproxen USP 500 mg and Esomeprazole Magnesium USP equivalent to Esomeprazole 20 mg.

SK+F

Manufactured by

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