Napro-A™ Plus

Tablet

Naproxen & Esomeprazole

COMPOSITION

Napro-A™ Plus 375: Each tablet contains delayed release Naproxen BP 375 mg and immediate release Esomeprazole Magnesium Trihydrate BP equivalent to Esomeprazole 20 mg.
Napro-A™ Plus 500: Each tablet contains delayed release Naproxen BP 500 mg and immediate release Esomeprazole Magnesium Trihydrate BP equivalent to Esomeprazole 20 mg.

PHARMACOLOGY

Napro-A™ Plus (Naproxen & Esomeprazole) is a combination of an immediate release Esomeprazole Magnesium layer on an enteric-coated (EC) Naproxen core. As a result, Esomeprazole is released first in the stomach, prior to the dissolution of Naproxen in the small intestine. The enteric coating prevents Naproxen release at P^H levels below 5 providing protection against possible local gastric toxicity.

Naproxen is a non-steroidal anti-inflammatory drug (NSAID) used as an analgesic and antipyretic. Naproxen is a propionic acid derivative and it inhibits the synthesis of prostaglandins, primarily by inhibiting the enzyme cyclo-oxygenase. Esomeprazole is a proton pump inhibitor and the S-isomer of Omeprazole. It suppresses gastric acid secretion by inhibiting the proton pump in the gastric parietal cell thus reducing gastric acidity.

INDICATIONS

Napro-A™ Plus (Naproxen & Esomeprazole) is indicated for the treatment of the signs and symptoms of osteoarthritis (OA), rheumatoid arthritis (RA) and ankylosing spondylitis (AS) and to decrease the risk of developing gastric ulcers in patients at risk for developing NSAID-associated gastric ulcers.

DOSAGE AND ADMINISTRATION

Route of administration:
The usual recommended dose for **Napro-A™ Plus:**

Recommended Strength	Medical Condition	Recommended (and Maximum) Dose per day
Napro-A™ Plus 375	Osteoarthritis, Rheumatoid Arthritis, Ankylosing Spondylitis and Dysmenorrhoea	**Twice daily**
Napro-A™ Plus 500		

The tablet must be swallowed whole with water but not be split, chewed, crushed or dissolved. Napro-A™ Plus should be taken at least 30 minutes before meal.

Geriatric use (>65 years)
Patients older than 65 years and frail or debilitated patients are more susceptible to a variety of adverse reactions from NSAIDs. The incidence of these adverse reactions increases with dose and duration of treatment. For such patients, to minimize the potential risk for an adverse event, the lowest effective dose should be used for the shortest possible duration.

Patients with renal impairment
In patients with mild to moderate renal impairment Naproxen/Esomeprazole should be used cautiously and renal function should be monitored closely. This preparation is contraindicated in patients with severe renal impairment or deteriorating renal disease.

Patients with hepatic impairment
In patients with mild to moderate hepatic impairment Naproxen/Esomeprazole should be used cautiously and hepatic function should be monitored closely. This preparation is contraindicated in patients with severe hepatic impairment.

Children (<18 years)
Naproxen-Esomeprazole is not recommended for use in children under 18 years of age.

Or as directed by the physician.

CONTRAINDICATIONS

Naproxen-Esomeprazole combination is contraindicated in:

- Patients with known hypersensitivity to Naproxen, Esomeprazole, substituted benzimidazoles or to any of the components/ excipients
- Patients with severe uncontrolled heart failure, inflammatory bowel disease, history of asthma, urticaria, or allergic-type reactions after taking Acetylsalicylic acid or other NSAIDs
- Patients with active gastric/duodenal/peptic ulcer, active GI bleeding, cerebrovascular bleeding or other bleeding disorders
- The peri-operative period in the setting of Coronary Artery Bypass Graft (CABG) surgery.

WARNING & PRECAUTION

Caution should be exercised in prescribing NSAIDs such as Naproxen to any patient with ischemic heart disease, cerebrovascular disease and/or congestive heart failure (NYHA II-IV).

SIDE EFFECTS

Common side effects : In general, **Napro-A™ Plus** is well tolerated. Most common side effects seen with this combination are erosive gastritis, dyspepsia, gastritis, upper abdominal pain, diarrhea, gastric ulcer, nausea, constipation etc.

Rare side effects :

USE IN PREGNANCY & LACTATION

It is contraindicated in the third trimester of pregnancy because of risk of premature closure of the ductus arteriosus and prolonged parturition. Caution should be exercised in prescribing this combination during the first and second trimesters of pregnancy.

USE IN CHILDREN & ADOLESCENTS

DRUG INTERACTIONS

Concomitant use NSAIDs may reduce the antihypertensive effect of ACE inhibitors, diuretics and beta-blockers. Concomitant use with methotrexate may increase methotrexate toxicity and with warfarin may result in increase risk of bleeding complications. Esomeprazole inhibits gastric acid secretion and may interfere with the absorption of drugs where gastric P^H is an important determinant of bioavailability (eg. Ketoconazole, Iron salts and Digoxin).

OVERDOSE

STORAGE

Store below 300 C and in dry place, protected from light.
Keep all medicines out of reach of children.

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PACKING

Napro-A™ Plus 375: Each box contains 3X10 tablets in alu-alu blister strips.

Napro-A™ Plus 500: Each box contains 3X10 tablets in alu-alu blister strips.

Further information is available on request

Manufactured by:
The ACME Laboratories Ltd.
Dhamrai, Dhaka, Bangladesh
For Health, Vigour and Happiness