

Each enteric coated tablet contains Naproxen BP 500 mg and Esomeprazole Magnesium Trihydrate BP equivalent to Esomeprazole 20 mg.

PHARMACOLOGY

Nimovo® is a preparation of Naproxen and Esomeprazole. Naproxen is a NSAID with analgesic and antipyretic activities. It inhibits prostaglandin synthesis. 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.

INDICATION

It 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 recommended dose is one tablet twice daily.

Do not split, chew, crush or dissolve the tablet. Nimovo® is to be taken at least 30 minutes before meals.

CONTRAINDICATION

It is contraindicated in patients with known hypersensitivity to any components of this products. It is also contraindicated in patients who have experienced asthma, urticaria, or allergic-type reactions after taking aspirin or other NSAIDs and for the treatment of peri-operative pain in the setting of coronary artery bypass graft (CABG) surgery.

WARNING AND PRECAUTION

Caution should be exercised in following conditions:

- Fatal cardiovascular thrombotic events like myocardial infarction, stroke, hypertension, congestive heart failure and edema.
- Serious GI adverse events.
- Hypomagnesaemia.
- Renal or hepatic insufficiency.

SIDE EFFECTS

The most common side effects are gastritis, erosive gastritis, dyspepsia, diarrhea, gastric ulcer, upper abdominal pain and nausea etc.

USE IN PREGNANCY AND LACTATION

The use of Nimovo® should be avoided in pregnancy and lactation unless the potential benefits to the other outweigh the possible risks to the fetus.

USE IN CHILDREN

Nimovo® should not be used in children under 12 years.

DRUG INTERACTION

ACE Inhibitors, diuretics and beta-blockers: may reduce the antihypertensive effect

Cyclosporin: increases the risk of nephrotoxicity.

Lithium: increases plasma level of lithium.

Methotrexate: may increase the serum levels of methotrexate.

Warfarin: may increase the risk of bleeding complications.

Digoxin: may increase the digoxin toxicity.
Clopidogrel: may decrease the exposure to the active metabolite of clopidogrel.

OVERDOSE

Overdose of Naproxen: Significant naproxen overdosage may be characterized by lethargy, drowsiness, epigastric pain, abdominal discomfort, heartburn, indigestion, nausea, transient alteration in liver function, hypoprothrombinemia, renal dysfunction, metabolic acidosis, apnea, vomiting etc.

Overdose of Esomeprazole: The major signs of acute toxicity were reduced motor activity, changes in respiratory frequency, tremor and intermittent clonic convulsions etc.

STORAGE CONDITION

Keep in a cool & dry place below 30°C temperature, protected from light and moisture. Keep out of the reach of children.

HOW SUPPLIED

Each box contains 40 tablets in Alu-Alu blister pack.

