

# NX Plus

Naproxen & Esomeprazole

## Composition

**NX Plus 375/20 Tablet:** Each tablet contains delayed release Naproxen Sodium USP equivalent to Naproxen 375 mg and immediate release Esomeprazole Magnesium Trihydrate USP equivalent to Esomeprazole 20 mg.

**NX Plus 500/20 Tablet:** Each tablet contains delayed release Naproxen Sodium USP equivalent to Naproxen 500 mg and immediate release Esomeprazole Magnesium Trihydrate USP equivalent to Esomeprazole 20 mg.

## Pharmacology

NX Plus consists of an immediate release Esomeprazole magnesium layer and an enteric coated Naproxen core. As a result Esomeprazole is released first into the stomach, prior to the dissolution of Naproxen in the small intestine.

Naproxen is a NSAID with analgesic and antipyretic properties. The mechanism of action of Naproxen is to inhibition of the prostaglandin synthesis. Esomeprazole is a proton pump inhibitor that suppresses gastric acid secretion by specific inhibition of the H<sup>+</sup>/K<sup>+</sup>-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, dysmenorrhoea and to decrease the risk of developing gastric ulcers in patients at risk of developing NSAID associated gastric ulcers.

## Dose and Administration

a) *Route of administration:* Oral

Carefully consider the potential benefits and risks of NX Plus and other treatment options before deciding to use NX Plus. Use the lowest effective dose for the shortest duration consistent with individual patient treatment goals. If a dose of Esomeprazole lower than a total daily dose of 40mg is more appropriate, a different treatment should be considered.

<b>Osteoarthritis, Rheumatoid Arthritis, Ankylosing Spondylitis and Dysmenorrhoea</b>	NX Plus 375/20	1 Tablet twice daily
	NX Plus 500/20	

\* Do not split, chew, crush or dissolve the tablet. NX Plus 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. As with other drugs used in the elderly use the lowest effective dose.

## Patients With Moderate to Severe Renal Impairment

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

## Hepatic Insufficiency

Monitor patients with mild to moderate hepatic impairment closely and consider a possible dose reduction based on the naproxen component of NX Plus. NX Plus is not recommended in patients with severe hepatic impairment because esomeprazole dosage should not exceed 20mg daily in these patients.

## Children

Dosage in children less than 18 years has not been established.

## Contra-indication

Knowing hypersensitivity to any component of NX Plus or substituted benzimidazoles. History of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs. Using during the peri-operative period in the setting of coronary artery bypass graft (CABG) surgery. Late pregnancy.

## Warning and Precaution

Patients with known CV disease/risk factors may be at greater risk. NX Plus should be used with caution in patients with fluid retention or heart failure.

## Side effect

a) *Common:* Erosive gastritis, dyspepsia.

b) *Rare:* Gastritis, diarrhea, gastric ulcer, upper abdominal pain, nausea etc.

## Use in pregnancy and lactation

*Pregnancy:* Pregnancy category C. In late pregnancy, it should be avoided because it may cause premature closure of the ductus arteriosus.

*Lactation:* NX Plus should not be used in nursing mothers due to the naproxen component.

## Use in children & adolescents

See the dose and administration.

## Drug interaction

a) *With medicine:* Concomitant use of NSAIDs may reduce the antihypertensive effect of ACE Inhibitors, diuretics, and beta-blockers.

Concomitant use of NX 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).

b) *With food & other:* No adequate data found.

## Overdose

There is no clinical data on overdosage with NX Plus.

*Overdose of Naproxen:* Significant naproxen overdosage may be characterized by lethargy, drowsiness, epigastric pain, abdominal discomfort, heartburn, indigestion, nausea, transient alterations 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

Store below 30°C. Protect from light and moisture. Keep all medicines out of reach of children.

## Packing

**NX Plus 375/20 Tablet:** Each box contains 30 (3X10's) tablets in alu-alu blister pack.

**NX Plus 500/20 Tablet:** Each box contains 30 (3X10's) tablets in alu-alu blister pack.