

Inflect-375/500

Naproxen & Esomeprazole

Composition

Inflect-375 Tablet: Each tablet contains delayed release Naproxen Sodium BP equivalent to Naproxen 375 mg and immediate release Esomeprazole Magnesium Trihydrate USP equivalent to Esomeprazole 20 mg.

Inflect-500 Tablet: Each tablet contains delayed release Naproxen Sodium BP equivalent to Naproxen 500 mg and immediate release Esomeprazole Magnesium Trihydrate USP equivalent to Esomeprazole 20 mg.

Description

Inflect tablet consists of an immediate release Esomeprazole magnesium layer and an enteric coated Naproxen core. The enteric coating prevents the release of Naproxen at pH levels below 5.5. 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 the Naproxen anion, like other NSAIDs, is not completely understood but may be related to prostaglandin synthetase inhibition. Esomeprazole is a proton pump inhibitor that suppresses gastric acid secretion by specific inhibition of the H⁺/K⁺-ATPase in the gastric parietal cells. 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.

Inflect tablet (Naproxen & Esomeprazole) is not recommended for initial treatment of acute pain as the absorption of naproxen is delayed compared to absorption from other naproxen-containing products.

Dosage & Administration

Rheumatoid Arthritis, Osteoarthritis, Ankylosing Spondylitis, and dysmenorrhea: One **Inflect tablet** 375 or 500 twice daily or as directed by the physician. Do not split, chew, crush, or dissolve the tablet. **Inflect tablet** is to be taken at least 30 minutes before meals. Carefully consider the potential benefits and risks of **Inflect tablet** and other treatment options before deciding to use **Inflect tablet**. 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 40 mg is more appropriate, a different treatment option should be considered.

Side-Effect

In general, **Inflect tablet** is well-tolerated. The most common adverse reactions include: erosive gastritis, dyspepsia, gastritis, diarrhea, gastric ulcer, upper abdominal pain & nausea, etc.

Contraindication

- Known hypersensitivity to any component of **Inflect tablet** or substituted benzimidazoles
- History of asthma, urticaria or other allergic-type reactions after taking aspirin or other
- Use during the peri-operative period in the setting of coronary artery bypass graft (CABG) surgery
- Late pregnancy

Precaution

NSAIDs, including naproxen, a component of **Inflect tablet** can lead to onset of new hypertension or worsening of preexisting hypertension, either of which may contribute to the increased incidence of Cardiovascular events. Patients with known Cardiovascular disease/risk factors may be at greater risk. **Inflect tablet** should be used with caution in patients with fluid retention or heart failure.

Elderly patients

Use with 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, administer the lowest effective dose.

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 **Inflect tablet**. **Inflect tablet** is not recommended in patients with severe hepatic impairment because esomeprazole dosage should not exceed 20 mg daily in these patients.

Children

The safety and efficacy of **Inflect Tablet** in children younger than 18 years have not been established. **Inflect Tablet** is therefore not recommended for use in children.

Use in Pregnancy & Lactation

In pregnancy:

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

In lactation:

Inflect tablet should not be used in nursing mothers due to the naproxen component.

Drug Interaction

Several studies conducted with this preparation have shown no interaction between the two components, Naproxen and Esomeprazole. The possible drug interactions are:

Cholestyramine: Cholestyramine can delay the absorption of Naproxen.

Methotrexate: NSAIDs could enhance the toxicity of Methotrexate.

Anticoagulants: Naproxen decreases platelet aggregation and may prolong bleeding time.

Selective Serotonin Reuptake Inhibitors: There is an increased risk of gastrointestinal bleeding when selective serotonin reuptake inhibitors are combined with NSAIDs including COX-2 selective inhibitors.

Other information concerning drug interactions:

- Naproxen is highly bound to plasma albumin. It thus has a theoretical potential for interaction with other albumin-bound drugs such as Sulphonylureas, Hydantoins and other NSAIDs.
- Concomitant use of NSAIDs may reduce the antihypertensive effect of ACE Inhibitors, diuretics, and beta-blockers
- Concomitant use of **Inflect tablet** 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 (e.g. ketoconazole, iron salts and digoxin).
- **Inflect tablet** can be administered with low-dose Aspirin therapy. But concurrent use of Aspirin and **Inflect tablet** may increase the risk of serious adverse reaction.

Overdose

There is no clinical data on overdosage with **Inflect tablet**.

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.

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

Storage

Store in cool and dry place, away from light. Keep out of the reach of children.

How Supplied

Inflect -375 Tablet: Each box contains 5 Alu-Alu blister strips of 4 tablets.

Inflect -500 Tablet: Each box contains 5 Alu-Alu blister strips of 4 tablets.

Manufactured by :

 **KEMIKO PHARMACEUTICALS LTD.**

Bangladesh