Napxon

Naproxen + Esomeprazole

Composition
Napxon 500 Tablet: Each delayed release tablet contains Naproxen BP 500 mg (enteric coated, delayed release core) and 20 mg of Esomeprazole as Esomeprazole magnesium trihydrate USP (immediate release coating).

Napxon 375 Tablet: Each delayed release tablet contains Naproxen BP 375 mg (enteric coated, delayed release core) and 20 mg of Esomeprazole as Esomeprazole magnesium trihydrate USP (immediate release coating).

Description
Napxon contains two active ingredients Naproxen and Esomeprazole. Naproxen is a nonsteroidal anti-inflammatory drug (NSAID) that works by reducing substances in the body that cause pain, inflammation and fever. Esomeprazole is a proton pump inhibitor that inhibits excess acid secretion in the stomach.

Indications
Napxon is indicated for the relief of sign 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 & Administration
Rheumatoid arthritis, Osteoarthritis and Ankylosing spondylitis: The dosage is one tablet twice daily of **Napxon 500** (500 mg Naproxen and 20 mg of Esomeprazole) or **Napxon 375** (375 mg Naproxen and 20 mg of Esomeprazole). The tablets are to be swallowed whole with liquid. Do not split, chew, crush or dissolve the tablet.
Napxon is to be taken at least 30 minutes before meals.
Geriatric patients: 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 amount of Naproxen in **Napxon**. **Napxon** should be avoided in patients with severe hepatic impairment.

Side effects
The most common side effects persist or become bothersome when using **Napxon** delayed release Tablets: Constipation, diarrhea, dizziness, drowsiness, gas, headache, heartburn, nausea, stomach bloating or upset.

Contraindications
Napxon is contraindicated in patients with known hypersensitivity to Naproxen, Esomeprazole or to any of the excipients. **Napxon** is contraindicated in patients who have experienced asthma, urticaria, or allergic-type reactions after taking aspirin or other NSAIDs. Severe, rarely fatal, anaphylactic like reactions to NSAIDs have been reported in such patients. Hypersensitivity reactions, eg, angioedema and anaphylactic reaction/shock, have been reported with esomeprazole use. **Napxon** is contraindicated for the treatment of peri-operative pain in the setting of coronary artery bypass graft (CABG) surgery. **Napxon** is contraindicated in patients in the late stages of pregnancy.

Precautions
Cardiovascular thrombotic events: Patients with known CV disease or risk factors for CV disease may be at greater risk. To minimize the potential risk for an adverse CV event in patients treated with an NSAID, the lowest effective dose should be used for the shortest duration possible.
Hypertension: NSAIDs should be used with caution in patients with hypertension.

Congestive heart failure and edema: Fluid retention, edema, and peripheral edema have been observed in some patients taking NSAIDs and should be used with caution in patients with fluid retention or heart failure.

Gastro-intestinal effects: NSAIDs can cause serious gastro-intestinal (GI) adverse effects including inflammation, bleeding, ulceration, and perforation of the stomach, small intestine, or large intestine, which can be fatal. While **Napxon** has been shown to significantly decrease the occurrence of gastric ulcers compared to Naproxen alone, ulceration and associated complications can still occur.

Active bleeding: When active and clinically significant bleeding from any source occurs in patients receiving **Napxon**, the treatment should be withdrawn.

Renal effects: Long-term administration of NSAIDs has resulted in renal papillary necrosis and other renal injury.

Advanced renal disease: No information is available from controlled clinical studies regarding the use of **Napxon** in patients with advanced renal disease. Therefore, treatment with **Napxon** is not recommended in these patients with advanced renal disease. If **Napxon** therapy must be initiated, close monitoring of the patient's renal function is advisable.

Anaphylactoid reactions: Anaphylactoid reactions may occur in patients without known prior exposure to either component of **Napxon**.

Hepatic effects: Hepatic abnormalities may be the result of hypersensitivity rather than direct toxicity. If clinical signs and symptoms consistent with liver disease develop, or if systemic manifestations occur (eg, eosinophilia, rash, etc.), **Napxon** should be discontinued. **Napxon** should be avoided in patients with severe hepatic impairment.

Concomitant NSAID use: **Napxon** contains Naproxen as one of its active ingredients. It should not be used with other Naproxen containing products since they all circulate in the plasma as the Naproxen anion. The concomitant use of **Napxon** with any dose of non-aspirin NSAID should be avoided due to the potential for increased risk of adverse reactions.

Bone fracture: Several studies and literature reports indicate that proton pump inhibitor (PPI) therapy is associated with an increased risk for osteoporosis-related fractures of the hip, wrist, or spine. Those patients with the highest risk received high-dose or long-term PPI therapy (a year or longer).

Pregnancy & Lactation
Pregnancy Category C. In late pregnancy, as with other NSAIDs, Naproxen should be avoided. **Napxon** should not be used in nursing mothers due to the Naproxen component.

Pediatric Use
The safety and efficacy of **Napxon** has not been established in children younger than 18 years.

Drug Interactions
Some of the medications that may lead to **Napxon** drug interactions include Angiotensin-converting enzyme inhibitors (ACE inhibitors), certain antifungals, certain diuretics, Iron supplements or medications, anticoagulant and antiplatelet drugs or otherwise increase the risk for bleeding, Thrombolytics, Some protease inhibitors, Selective serotonin reuptake inhibitor (SSRI) or serotonin-norepinephrine reuptake inhibitor (SNRI) medications.

Storage
Store in a cool and dry place, protected from light.

Packaging
Napxon 500 Tablet: Each box contains 4X8's tablets in alu-alu blister pack.
Napxon 375 Tablet: Each box contains 4X8's tablets in alu-alu blister pack.

Manufactured by
ZISKA PHARMA
Ziska Pharmaceuticals Ltd.
Kaliakoir, Gazipur, Bangladesh