

Anaflex® Max

Naproxen + Esomeprazole

Description

Anaflex® Max is a preparation of Naproxen and Esomeprazole combination. Naproxen is a non-steroidal anti-inflammatory drug (NSAID) with analgesic, anti-inflammatory and antipyretic properties. It works by reducing the levels of prostaglandins. Esomeprazole is a proton pump inhibitor that inhibits the final step of the gastric acid formation process.

Indications

Anaflex® Max is indicated for the relief of sign and symptoms of Osteoarthritis, Rheumatoid Arthritis, Ankylosing Spondylitis and to reduce the risk of developing gastric ulcers in patients at risk of developing NSAID-associated gastric ulcers.

Dosage and administration

Anaflex® Max is to be taken at least 30 minutes before meals.

Rheumatoid Arthritis, Osteoarthritis and Ankylosing Spondylitis:

The dosage is one tablet twice daily of (375 mg Naproxen + 20 mg Esomeprazole) or (500 mg Naproxen + 20 mg Esomeprazole).

Geriatric Patients: Use cautiously 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.

Pediatric Patients: The safety and efficacy of this drug has not been established in children younger than 18 years. Therefore it is not recommended for use in children.

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

Hepatic insufficiency: It should be avoided in patients with severe hepatic impairment.

Use in pregnancy and lactation

Pregnancy Category C. In late pregnancy, as with other NSAIDs, Naproxen should be avoided because it may cause premature closure of the ductus arteriosus in the fetus. It should not be used in nursing mothers due to the Naproxen component.

Side effect

The most common side effects are erosive gastritis, dyspepsia, gastric ulcer, upper abdominal pain, nausea, esophagitis, constipation, erosive duodenitis, diarrhea, dizziness, drowsiness, peripheral edema, and headache.

Precaution

Patients with known cardiovascular disease/risk factors may be at greater risk. This combination should be used with caution in patients with fluid retention or heart failure.

Contraindication

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

Overdose

There is no clinical data on overdosage with this combination. Significant Naproxen overdosage may be characterized by lethargy, dizziness, drowsiness, epigastric pain, abdominal discomfort, heartburn, indigestion, nausea, transient alterations in liver function, hypoprothrombinemia, renal dysfunction, metabolic acidosis, apnea, disorientation or vomiting. Gastrointestinal bleeding can also occur. Significant Esomeprazole overdosage may be characterized by confusion, drowsiness, blurred vision, tachycardia, nausea, diaphoresis, flushing, headache, dry mouth, and other adverse reactions.

Drug interaction

Several studies conducted with Naproxen & Esomeprazole combination have shown no interaction between the two components. Drug interactions may be with ACE inhibitors, certain antifungals, certain diuretics, Iron supplements, anticoagulants and antiplatelets or otherwise increase the risk for bleeding, thrombolytics, some protease inhibitors, selective serotonin reuptake inhibitor (SSRI) or serotonin-norepinephrine reuptake inhibitor (SNRI) medications.

Pharmaceutical precautions

Store below 25°C protected from light & moisture. Keep away from the reach of children.

Presentation

Anaflex® Max 375 tablet: Each delayed release tablet contains Naproxen BP 375 mg & Esomeprazole 20 mg as Magnesium Trihydrate USP.

Anaflex® Max 500 tablet: Each delayed release tablet contains Naproxen BP 500 mg & Esomeprazole 20 mg as Magnesium Trihydrate USP.

Package quantities

Anaflex® Max 375 tablet: Carton of 50 tablets in blister pack.

Anaflex® Max 500 tablet: Carton of 50 tablets in blister pack.

® Registered Trade Mark



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