Only for the use of Medical Professionals

Anaflex® Max

Naproxen + Esomeprazole

Composition

Anaflex® Max 375 mg Tablet: Each delayed release tablet contains Naproxen BP 375 mg and Esomeprazole 20 mg as Magnesium Trihydrate USP.
Anaflex® Max 500 mg Tablet: Each delayed release tablet contains Naproxen BP 500 mg and Esomeprazole 20 mg as Magnesium Trihydrate USP.

Pharmacology

Anaflex® Max is a preparation of Naproxen and Esomeprazole. Naproxen is a NSAID with analgesic and antipyretic properties. The mechanism of action of Naproxen is like that of other NSAIDs, 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 cell. By acting specifically on the proton pump, Esomeprazole blocks the final step in acid production, thus reducing gastric acidity.

Indication

Anaflex® Max is indicated for the relief of signs and symptoms of osteoarthritis, rheumatoid arthritis, 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

Carefully consider the potential benefits and risks of **Anaflex® Max** and other treatment options before deciding to use **Anaflex® Max**. 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 should be considered.

Rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, and dysmenorrhoea: Anaflex® Max 375 or 500 one tablet twice daily or as directed by the physician.

Do not split, chew, crush, or dissolve the tablet. **Anaflex® Max** 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 **Anaflex® Max**. This combination is not recommended in patients with severe hepatic impairment because esomeprazole dosage should not exceed 20 mg daily in these patients.

Contraindication

Contraindicated in known hypersensitivity to any component of this combination or substituted benzimidazoles, history of asthma, urticaria or other allergic type reactions after taking aspirin or other NSAIDs, use during the peri-operative pain in the setting of coronary artery bypass graft (CABG) surgery and late pregnancy.

Warning and precaution

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

Side effects

In general, this combination is well tolerated. The most common adverse reactions in clinical trials (> 5%): erosive gastritis, dyspepsia, esophagitis, diarrhea, gastric ulcer, upper abdominal pain and nausea.

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: This combination should not be used in nursing mothers due to the naproxen component.

Use in children and adolescents

The safety and efficacy of this drug in children less than 18 years has not been established.

Drug interaction

Concomitant use of NSAIDs may reduce the antihypertensive effect of ACE Inhibitors, diuretics, and beta-blockers. Concomitant use of this combination 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).

Overdose

There is no clinical data on overdosage with this combination. Overdose of naproxen: significant naproxen overdose may be characterized by lethargy, drowsiness, epigastric pain, abdominal discomfort, heartburn, indigestion, nausea, transient alterations in liver function, hypoprothrombinemia, renal dysfunction, metabolic acidosis, apnea, and 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 below 25ºC protected from light & moisture. Keep away from the reach of children.

Packing

Anaflex® Max 375 mg Tablet: Carton of 50 tablets in blister.
Anaflex® Max 500 mg Tablet: Carton of 50 tablets in blister.

® Registered Trade Mark

Manufactured by

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for

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