Nabufast

Nabumetone USP

Composition

Nabufast 500 Tablet: Each film coated tablet contains Nabumetone USP 500 mg.

Pharmacology

Nabufast is a preparation of Nabumetone which is a non-steroidal anti-inflammatory drug (NSAID) that exhibits anti-inflammatory, analgesic and antipyretic properties in pharmacologic studies. As with other non-steroidal anti-inflammatory agents, its mode of action is not known; however, the ability to inhibit prostaglandin synthesis may be involved in the anti-inflammatory effect. The parent compound is a prodrug, which undergoes hepatic biotransformation to the active component, 6-methoxy-2-naphthylacetic acid (6MNA), that is a potent inhibitor of prostaglandin synthesis.

Indications

Nabufast is indicated for acute and chronic treatment of signs and symptoms of Osteoarthritis and Rheumatoid Arthritis.

Dose and Administration

The recommended starting dose of Nabufast is 1000 mg taken as a single dose with or without food. Some patients may obtain more symptomatic relief from 1500 mg to 2000 mg per day. Nabufast can be given in either a single or twice daily dose. Dosages greater than 2000 mg per day have not been studied. The lowest effective dose should be used for chronic treatment.

Patients with renal impairment: Caution should be used in prescribing Nabumetone to patients with moderate or severe renal insufficiency. The maximum starting doses of Nabumetone in patients with moderate or severe renal insufficiency should not exceed 750 mg or 500 mg, respectively once daily. Following careful monitoring of renal function in patients with moderate or severe renal insufficiency, daily doses may be increased to a maximum of 1500 mg and 1000 mg respectively.

Contraindications

Nabumetone is contraindicated in patients with known hypersensitivity to Nabumetone or its excipients. It should not be given to patients who have experienced asthma, urticaria, or allergic type reactions after taking Aspirin or other NSAIDs. Nabumetone is contraindicated for the treatment of peri-operative pain in the setting of coronary artery bypass graft (CABG) surgery.

Warning and Precautions

As a class, NSAIDs have been associated with renal papillary necrosis and other abnormal renal pathology during long term administration to animals. A second form of renal toxicity often associated with NSAIDs is seen in patients with conditions leading to a reduction in renal blood flow or blood volume, where renal prostaglandins have a supportive role in the maintenance of renal perfusion. In these patients, administration of an NSAID results in a dose-dependent decrease in prostaglandin synthesis and secondarily, in a reduction of renal blood flow, which may precipitate overt renal decompensation. Patients at greatest risk of this reaction are those with impaired renal function, heart failure, liver dysfunction, those taking diuretics and the elderly. Discontinuation of NSAID therapy is typically followed by recovery to the pretreatment state.

Side Effects

Most common side effects of Nabumetone include diarrhea, dyspepsia, abdominal pain, constipation, flatulence, nausea, dry mouth, gastritis, stomatitis, vomiting, dizziness, headache, fatigue, increased sweating, insomnia, nervousness, somnolence, pruritus, rash, tinnitus and edema.

Use in Pregnancy and Lactation

Pregnancy: Nabumetone is a pregnancy category C drug. There are no adequate and well controlled studies in pregnant women. This drug should be used during pregnancy only if clearly needed. Because of the known effect of prostaglandin synthesis inhibiting drugs on the human fetal cardiovascular system (closure of ductus arteriosus), use of Nabumetone during the third trimester of pregnancy is not recommended.

Lactation: Nabumetone is not recommended for use in nursing mothers because of the possible adverse effects of prostaglandin synthesis inhibiting drugs on neonates.

Use in Children and Adolescents: Safety and effectiveness in pediatric patients have not been established.

Drug Interactions

Drug interaction with medication: Caution should be exercised when administering Nabumetone with Warfarin since interactions have been seen with other NSAIDs. Concomitant administration of an aluminium containing antacid had no significant effect on the bioavailability of Nabumetone.

Drug interaction with food and others: When administered with food or milk, there is more rapid absorption; however, the total amount of Nabumetone in the plasma is unchanged.

Overdose

Patients should be managed by symptomatic and supportive care following a NSAIDs overdose. There are no specific antidotes. Emesis and/or activated charcoal and/or osmotic cathartic may be indicated in patients seen within 4 hours of ingestion with symptoms or following a large overdose. Forced diuresis, alkalinization of urine, hemodialysis or hemoperfusion may not be useful due to high protein binding.

Storage

Store at a temperature of below 30°C, protect from light & moisture. Keep out of reach of children.

How supplied

Nabufast 500 Tablet: Each box contains 30 tablets in Alu-Alu blister pack.

Pharmasia

Manufactured by

Pharmasia Limited

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