Nabumet™

Nabumetone BP Film Coated Tablet

DESCRIPTION

Nabumet™ is a preparation of Nabumetone. Nabumetone 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

Indicated for acute and chronic treatment of signs and symptoms of osteoarthritis and rheumatoid arthritis.

DOSAGE AND ADMINISTRATION

Osteoarthritis and Rheumatoid Arthritis: The recommended starting dose is 1,000 mg taken as a single dose with or without food. Some patients may obtain more symptomatic relief from 1,500 mg to 2,000 mg per day. Nabumetone can be given in either a single or twice-daily dose. Dosages greater than 2,000 mg per day have not been studied. The lowest effective dose should be used for chronic treatment. 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 1,500 mg and 1,000 mg, respectively.

CONTRAINDICATIONS

- Hypersensitivity
- NSAIDs induce asthma, urticaria, or other allergic-type reactions.

SIDE EFFECTS

- Gastrointestinal: Diarrhea, dyspepsia, abdominal pain, constipation, flatulence, nausea, positive stool guaiac, dry mouth, gastritis, stomatitis, vomiting.
- Central Nervous System: Dizziness, headache, fatigue, increased sweating, insomnia, nervousness, somnolence.
- Dermatologic: Pruritus, rash.
- Special Senses: Tinnitus.
- Miscellaneous: Edema

PRECAUTION AND WARNING

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.

USE IN PREGNANCY AND LACTATION

Pregnancy: Pregnancy Category C. There are no adequate, 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.

PHARMACEUTICAL PRECAUTION

Do not store above 30 °C temperature. Keep away from light and wet place. Keep out of reach of children.

PACKAGING

Nabumet™ 500 Tablet:

Box containing 3 strips of 10 tablets each. Each Film Coated Tablet contains Nabumetone BP 500 mg.

Nabumet™ 750 Tablet:

Box containing 4 strips of 6 tablets each. Each Film Coated Tablet contains Nabumetone BP 750 mg.

SK+F

Manufactured by

ESKAYEF PHARMACEUTICALS LTD.

TONGI, GAZIPUR, BANGLADESH

TM TRADEMARK

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