Nabufen

Nabumetone USP

Composition:
Nabufen 500 Tablet: Each film coated tablet contains Nabumetone USP 500 mg.
Nabufen 750 Tablet: Each film coated tablet contains Nabumetone USP 750 mg.

Description
Nabufen is a preparation of Nabumetone which is a nonsteroidal anti-inflammatory drug (NSAID) that exhibits anti-inflammatory, analgesic and antipyretic properties.

Pharmacology
Like other non-steroidal anti-inflammatory agents, the mode of action of Nabumetone 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), which is a potent inhibitor of prostaglandin synthesis.

Indications
Nabumetone is indicated for acute and chronic treatment of signs and symptoms of osteoarthritis and rheumatoid arthritis.

Dosage and Administrations
• ***For 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. The lowest doses should be used for chronic treatment.
• ***For Patients with Renal Impairment:*** Caution should be taken in prescribing Nabumetone to patients with moderate to severe renal insufficiency. A maximum starting dose of Nabumetone in patients with moderate to severe renal insufficiency should not exceed 750mg or 500 mg, respectively once daily. Following careful monitoring of renal function in patients with moderate to severe renal insufficiency, daily doses may be increased to a maximum of 1,500 mg and 1,000 mg, respectively.

Contraindications
Nabumetone is contraindicated for:
• Hypersensitivity to Nabumetone.
• NSAIDs induce asthma, urticaria, or other allergic-type reaction.

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. The 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 prostaglandin synthesis, 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 NSAIDs therapy is typically followed by recovery to the pretreatment state.

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.

Use in Specific Populations
Pregnancy: Pregnancy Category C. There are no adequate, well-controlled studies in pregnant women. Use of Nabumetone during the third trimester of pregnancy is not recommended.
Lactation: Nabumetone is not recommended for use in nursing mothers.
Labor and Delivery: The effects of Nabumetone on labor and delivery in women are not known.
Pediatric Use: Safety and effectiveness in pediatric patients have not been established.
Geriatric Use: No differences were found in overall efficacy or safety between more than 65 years older patients and younger patients.

Drug interactions
Reports suggest that NSAIDS may diminish the antihypertensive effect of ACE inhibitors.

Overdose
Symptoms following acute NSAIDs overdoses are usually limited to lethargy, drowsiness, nausea, vomiting and epigastric pain, which are generally reversible with supportive care. Gastrointestinal bleeding can occur. Hypertension, acute renal failure, respiratory depression and coma may occur but are rare. Anaphylactic reactions have been reported with therapeutic ingestion of NSAIDs and may occur following an overdose.

Storage
Do not store above 30° C. Protect from light and keep out of the reach of children.

Packaging
Nabufen 500 Tablet: Each box contains 4 x 8's tablets in blister strips.
Nabufen 750 Tablet: Each box contains 4 x 8's tablets in blister strips.

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