Naburel

Nabumetone USP

COMPOSITION

Naburel 500 mg Tablet: Each film-coated tablet contains Nabumetone USP 500 mg.
Naburel 750 mg Tablet: Each film-coated tablet contains Nabumetone USP 750 mg.

PHARMACOLOGY

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

Naburel is indicated for relief of signs and symptoms of osteoarthritis and rheumatoid arthritis.

DOSAGE & ADMINISTRATIONS

Route of administration: Oral
Dosage: Osteoarthritis and Rheumatoid Arthritis: The recommended starting dose 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. Naburel 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.

CONTRAINDICATIONS

- Hypersensitivity to Nabumetone or any of its components.
- NSAIDs induced asthma, urticaria, or allergic type reactions.

WARNING & PRECAUTIONS

Long-term administration of NSAIDs has resulted in renal papillary necrosis and other renal injury. Renal toxicity has also been seen in patients in whom renal prostaglandins have a compensatory 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. NSAIDs may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. This risk may increase with duration of use. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at a greater risk. NSAIDs cause an increased risk of serious gastrointestinal adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal.

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

Use in pregnancy: Pregnancy Category C. There are no adequate, well-controlled studies in pregnant women. This drug should be used during pregnancy only if dearly needed. Use of Nabumetone during the third trimester of pregnancy is not recommended.
Use in renal impairment: Caution should be taken 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.
Use in 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 & adolescents: Safety and effectiveness in pediatric patients have not been established.

DRUG INTERACTIONS

Reports suggest that NSAIDs may diminish the antihypertensive effect of ACE-inhibitors. This interaction should be given consideration in patients taking NSAIDs concomitantly with ACE-inhibitors.

OVERDOSAGE

Symptoms following acute NSAIDs overdoses are usually limited to lethargy, drowsiness, nausea, and vomiting. and epigastric pain, which is generally reversible with supportive care. Gastrointestinal bleeding can occur. Hypertension, acute renal failure, respiratory depression, and coma may occur but are rare. Anaphylactoid reactions have been reported with therapeutic ingestion of NSAIDs and may occur following an overdose. Patients should be managed by symptomatic and supportive care following a NSAID overdose. There are no specific antidotes. Emesis and/or activated charcoal (60 to 100 grams in adults, 1 to 2 g/kg in children). and/or osmotic cathartic may be indicated in patients seen within 4 hours of ingestion with symptoms or following a large overdose (5 to 10 times the usual dose) Forced diuresis, alkalinization of urine, hemodialysis, or hemoperfusion may not be useful due to high protein binding. There have been overdoses of up to 25 grams of Nabumetone reported with no long-term sequelae following standard emergency treatment (i.e. activated charcoal gastric lavage, IV H2-blockers, etc.).

STORAGE

- Store below 30°C, keep in dry place & protect from light.
- Keep out of reach of children.

PACKING

Naburel 500 mg Tablet: Each box contains 30's Tablets in blister pack.
Naburel 750 mg Tablet: Each box contains 20's Tablets in blister pack.

Manufactured by:
ARISTOPHARMA LTD.
Shampur-Kadamtali I/A, Dhaka-Bangladesh

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