Flamfix™

Nabumetone USP

PRESENTATION

Flamfix™ 500: Each film-coated tablet contains Nabumetone USP 500 mg.
Flamfix™ 750: Each film-coated tablet contains Nabumetone USP 750 mg.

DESCRIPTION

Nabumetone is a nonsteroidal anti-inflammatory drug (NSAID) that exhibits anti-inflammatory, analgesic, and antipyretic properties in pharmacologic studies. 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.

INDICATION

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

DOSAGE & ADMINISTRATION

Osteoarthritis and Rheumatoid Arthritis: The recommended starting dose is 1000 mg taken as a single dose with or without food. To obtain more symptomatic relief patients may take dose from 1500 mg to 2000 mg per day. Flamfix can be given in either a single or twice-daily dose. For chronic use 1000 mg daily dose should be taken.

USE IN SPECIAL POPULATION

Renal Insufficiency: 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 1,000 mg, respectively.

Hepatic Impairment: Nabumetone should be used with caution in patients with severe hepatic impairment.

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

Geriatric Use: No overall differences in efficacy or safety were observed between older patients and younger ones.

SIDE EFFECT

Gastrointestinal: Diarrhea (14%), dyspepsia (13%), abdominal pain (12%), constipation, flatulence, vomiting, nausea, positive stool guaiac, dry mouth, gastritis, stomatitis.

Central *Nervous System:* Dizziness, headache, fatigue, increased sweating, insomnia, nervousness, somnolence.

Dermatologic: Pruritus, rash.

Miscellaneous: Edema, Tinnitus.

CONTRAINDICATION

Nabumetone is contraindicated in patients who have previously exhibited hypersensitivity to it. Nabumetone is contraindicated in patients in whom Nabumetone, aspirin, or other NSAIDs induced asthma, urticarial, or other allergic-type reactions.

DRUG INTERACTION

Caution should be exercised when administering Nabumetone with Warfarin. Because of its affinity for protein, active metabolite 6-MNA may displace other protein-bound drugs from their binding site.

USE IN PREGNANCY & LACTATION

Pregnancy Category C.

There are no adequate, well-controlled studies in pregnant women. This drug should be used during pregnancy only if clearly needed. Use of Nabumetone during the third trimester of pregnancy is not recommended.

Labor and Delivery: The effects of Nabumetone on labor and delivery in women are not known.

Nursing Mothers: Nabumetone is not recommended for use in nursing mothers. It is not known whether Nabumetone or its metabolites are excreted in human milk.

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, anaphylactoid reactions may occur. Patients should be managed by symptomatic and supportive care following a NSAIDs overdose. 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).

STORAGE CONDITION

Store below 25° C, protect from light & moisture. Keep out of the reach of children.

HOW SUPPLIED

Flamfix™ 500: Each box contains 30 tablets in blister pack.
Flamfix™ 750: Each box contains 24 tablets in blister pack.

Manufactured by

SQUARE
PHARMACEUTICALS PLC.
BANGLADESH