

Elivier™

Nabumetone Tablet

Presentation

Elivier™ 500: Each tablet contains Nabumetone USP 500 mg.

Elivier™ 1000 DT: Each dispersible tablet contains Nabumetone USP 1000 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 and 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. Elivier can be given in either a single or twice-daily dose. For chronic use 1000 mg daily dose should be taken.

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.

Preparation (Elivier™ 1000 DT)

Put one 1000 mg dispersible tablet in one glass of water and stir to dissolve.

Do not use hot water. Should be taken immediately after dissolving in water.

If any precipitate remains that should be taken too.



Side Effects

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, urticaria, or other allergic-type reactions.

Drug Interactions

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 and 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.

Nursing Mothers: Nabumetone is not recommended for use in nursing mothers.

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, 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

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

Commercial Pack

Elivier™ 500: Each box contains 3 blister strips of 10 tablets.

Elivier™ 1000 DT: Each box contains 4 blister strips of 6 tablets.