Aponia

Nabumetone USP Tablet

Composition
Aponia 500 Tablet: Each film coated tablet contains Nabumetone USP 500 mg.
Aponia 750 Tablet: Each film coated tablet contains Nabumetone USP 750 mg.
Aponia 1000 Tablet: Each film coated tablet contains Nabumetone USP 1000 mg.

Pharmacology
Nabumetone is a naphthylalkanone. It is a non-selective prostaglandin G/H synthase (a.k.a. cyclooxygenase or COX) inhibitor that acts on both prostaglandin G/H synthase 1 and 2 (COX-1 and COX-2). Prostaglandin G/H synthase catalyzes the conversion of arachidonic acid to prostaglandin G2 and prostaglandin G2 to prostaglandin H2. Prostaglandin H2 is the precursor to a number of prostaglandins involved in fever, pain, swelling, inflammation and platelet aggregation. The parent compound is a prodrug that undergoes hepatic biotransformation to the active compound, 6-methoxy-2-naphthylacetic acid (6MNA). The analgesic, antipyretic and anti-inflammatory effects of NSAIDs occur as a result of decreased prostaglandin synthesis.
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, most likely through binding to the COX-2 and COX-1 receptors.

Indication
For acute and chronic treatment of signs and symptoms of osteoarthritis and rheumatoid arthritis.

Dose and Administration
a) Route of adminstration: Oral
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. Nabumetone 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 1000 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.

Contra-indication
Nabumetone is contraindicated in patients with known hypersensitivity to Nabumetone or its excipients. Nabumetone should not be given to patients who have experienced asthma, urticaria or allergic type reactions after taking aspirin or other NSAIDs. Severe, rarely fatal, anaphylactic-like reactions to NSAIDs have been reported in such patients. Nabumetone is contraindicated for the treatment of peri-operative pain in the setting of coronary artery bypass graft (CABG) surgery.

Warning & Precaution
Nabumetone cannot be expected to substitute for corticosteroids or to treat corticosteroid insufficiency. Abrupt discontinuation of corticosteroids may lead to disease exacerbation. Patients on prolonged corticosteroid therapy should have their therapy tapered slowly if a decision is made to discontinue corticosteroids. The pharmacological activity of Nabumetone in reducing fever and inflammation may diminish the utility of these diagnostic signs in detecting complications of presumed noninfectious, painful conditions.

Side Effects
a) Common: Diarrhea, dyspepsia, abdominal pain, constipation, flatulence, vomiting, nausea, dry mouth, gastritis and stomatitis.
b) Rare: Anemia, Depression, Blurred Vision and Mood Change.

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. Use of Nabumetone during the third trimester of pregnancy is not recommended.
Labor and Delivery: The effects of Nabumetone on labor pain 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.

Use in Children and Adolescents
It is not known if Nabumetone is safe and effective in children.

Drug Interactions
a) With medicine: 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.
b) With food & others: Interacted with heavily salted foods.

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, anaphylactic 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
Store below 30°C. Protect from light and moisture. Keep all medicines out of reach of children.

Packing
Aponia 500 Tablet: Each box contains 30 (3X10's) tablets alu-alu blister.
Aponia 750 Tablet: Each box contains 20 (2X10's) tablets alu-alu blister.
Aponia 1000 Tablet: Each box contains 10 (1X10's) tablets alu-alu blister.

Manufactured by
ONE PHARMA LTD.
C-23-24, BSCIC I/A
Bogura, Bangladesh

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