

Nabuxan Tablets

Nabumetone

Composition:

Each film coated tablet contains: Nabumetone 500mg

Properties:

Nabumetone is a member of non-steroidal anti-inflammatory drugs.

The chemical name for nabumetone is 4-(6-methoxy-2-naphthyl)-2-butanone

Nabumetone is an odourless, white to off-white crystalline substance.

Nabumetone is a non-steroidal anti-inflammatory drug with analgesic and antipyretic properties.

Nabumetone has been developed as an analgesic because it is well absorbed

Indications:

Nabuxan is indicated for the treatment of:

Rheumatoid arthritis

Osteoarthritis

Ankylosing spondylitis.

Dosage and administration:

Osteoarthritis, Rheumatoid Arthritis and Ankylosing spondylitis.

The recommended starting dose is 1000mg taken as a single dose with or without food.

Some patients may obtain more symptomatic relief from 1500mg to 2000 mg per day.

Nabuxan can be given in either a single or twice-daily dose.

The lowest effective dose should be used for chronic treatment.

Contraindications:

The drug is contraindicated in patients who have had allergic reactions to Nabumetone, Active peptic ulcer.

Adverse reactions:

Adverse reaction information was derived from blinded-controlled and open-labeled clinical trials and from worldwide marketing experience. In the description below, rates of the more common events (less than 1%) represent results of U.S. clinical studies

The most frequently reported adverse reactions were related to the gastrointestinal tract. They were diarrhea dyspepsia and abdominal pain.

Incidence equal to 1%.

Gastrointestinal: Diarrhea, dyspepsia, abdominal pain, constipation, flatulence. nausea

Dermatologic: Pruritus, rash

Miscellaneous: Edema, Headache.

Incidence <1%:

Gastrointestinal: Anorexia, dysphagia, increased appetite, liver function abnormalities.

Central Nervous System: anxiety, confusion, depression, malaise, tremor and vertigo.

Dermatologic: Bullous eruptions, photosensitivity, urticaria.

Cardiovascular: Vasculitis

Metabolic: Weight gain.

Special Senses: Abnormal vision

Hypersensitivity: Anaphylactic reaction, anaphylaxis.

Drug interactions:

In vitro studies have shown that, because of its affinity for protein, 6MNA may displace other protein-bound drugs from their binding site. Caution should be exercised when administering nabumetone with Warfarin since interactions have been seen with other NSAIDs.

Special warning and precautions:

General Renal Effects: As with other non-steroidal anti-inflammatory drugs, long-term administration of Nabumetone, there have been reports of acute interstitial nephritis with hematuria, proteinuria, and occasionally nephritic syndrome

Hepatic Effects:

As with other NSAIDs, borderline elevations of one or more liver function tests may occur in up to 15% of patients. These abnormalities may progress, may remain essentially unchanged, or may return to normal with continued therapy.

The ALT (SGPT) test is probably the most sensitive indicator of liver dysfunction. Meaningful (3 times the upper limit of normal) elevations of ALT (SGPT) or AST (SGOT) have occurred in controlled clinical trials of Nabumetone in less than 1% of patients. A patient with symptoms and/or signs suggesting liver dysfunction, or in whom an abnormal liver test has occurred, should be evaluated for evidence of the development of a more severe hepatic reaction while on nabumetone therapy. Severe hepatic reactions including jaundice have been reported with other NSAIDs.

Laboratory Tests:

Because serious GI tract ulceration and bleeding can occur without warning symptoms, physicians should follow chronically treated patients for the signs and symptoms of ulceration and bleeding and should inform them of the importance of this follow-up. Risk of GI Ulceration, Bleeding and Perforation with NSAID Therapy. Impairment of Fertility. Nabumetone did not impair fertility of male or female rats treated orally at doses of 320 mg/kg/day (1888mg/m²) before mating.

Pregnancy, Teratogenic Effects, Pregnancy Category C:

Nabumetone did not cause any teratogenic effect in rats given up to 400 mg/kg (2360 mg/m²) and in rabbits up to 300 mg/kg (3540mg/m²) orally. However, increased post implantation loss was observed in rats at 100mg/kg (590mg/m²) orally and at higher doses (equal to the average human exposure to 6MNA at the maximum recommended human dose). There are no adequate, well-controlled studies in pregnant women this drug should be used during pregnancy only if clearly needed.

Because of the known effect of prostaglandin-synthesis-inhibiting drugs on the human fetal cardiovascular system (closure of ductus arteriosus), use of nabumetone during the third trimester of pregnancy is not recommended.

Nursing Mothers:

Nabumetone is not recommended for use in nursing mothers because of the possible adverse effects of prostaglandin-synthesis-inhibiting drugs on neonates. It is not known whether nabumetone or its metabolites are excreted in human milk; however 6MNA is excreted in the milk of lactating rats.

Paediatric Use:

Nabumetone is not recommended for use in children because the safety and efficacy in children have not been established.

Overdosage:

Since only one case of nabumetone overdose has been reported, the experience is limited. If acute overdose occurs, it is recommended that the stomach be emptied by vomiting or lavage and general supportive measures be instituted, as necessary. In addition, the use of activated charcoal, up to 60 grams, may effectively reduce nabumetone absorption. Co-administration of nabumetone with charcoal to man has resulted in an 80% decrease in maximum plasma concentrations of the active metabolite. The one overdose occurred in a 17-years-old female patient who had a history of abdominal pain and was hospitalized for increased abdominal pain following ingestion of 30 nabumetone tablets (15 grams total). Stools were negative for occult blood and there was no fall in serum hemoglobin concentration. The patient had no other symptoms. She was given an H₂-receptor antagonist and discharged from the hospital without sequela.

Contraindications:

Nabumetone is contraindicated in patients who have previously exhibited hypersensitivity to it.

Storage: Store in a cool and dry place.

Keep out of reach of children

Package:

Boxes of 10 Film Coated Tablets.

Produced by:

UNI PHARMA

El Obour City, Cairo-Egypt.