

Mobicam®

Tenoxicam
Tablet

Description

Tenoxicam is a non-steroidal antiinflammatory drug (NSAID) with anti-inflammatory, analgesic, antipyretic properties and it also inhibits platelet aggregation. Tenoxicam inhibits prostaglandin biosynthesis and used in the treatment of inflammatory and degenerative disorders of the musculoskeletal system.

Indications

Tenoxicam is indicated for the symptomatic treatment of rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, acute gout, and extra-articular inflammations such as tendinitis, bursitis and peri-arthritis of the shoulders or hips. It is also indicated in musculoskeletal & postoperative pain and in primary dysmenorrhea.

Dosage And Administration

For all indications (except primary dysmenorrhea, post-operative pain and acute gout) the usual recommended dose is 20 mg once daily. Tenoxicam should be taken at the same time of day; in case of rheumatoid arthritis Tenoxicam should be taken at night to relieve the morning stiffness. The recommended dose for primary dysmenorrhea is 20 to 40 mg once daily. For post-operative pain the recommended dose is 40 mg once daily up to five days and for acute attacks of gout the recommended dose is 40 mg once daily for two days followed by 20 mg once daily for a further five days.

Note: Tenoxicam is not recommended for use in patients under 16 years of age.

Pregnancy and Lactation

The safety of Tenoxicam during pregnancy has not been established therefore it should be used with caution during pregnancy and only if the benefit to the mother is greater than the risk of the fetus. There is no information available about the safety of Tenoxicam during breastfeeding therefore it should not be used during lactation.

Contraindications

Tenoxicam should not be administered to patients with active peptic ulcer or active inflammatory diseases of the gastrointestinal tract. Tenoxicam is contraindicated in patients who have shown hypersensitivity to the drug. It should not be used in patients in whom acute asthmatic attacks, urticaria, rhinitis or other allergic manifestations are precipitated by ASA or other nonsteroidal anti-inflammatory agents. Fatal anaphylactoid reactions have occurred in such individuals. Before anesthesia or surgery, Tenoxicam should not be given to elderly patients, to patients at risk of renal failure, or to patients with increased risk of bleeding, because of an increased risk of acute renal failure and possibility of impaired hemostasis. Tenoxicam is relatively contraindicated in patients with liver dysfunction.

Adverse Reactions

Tenoxicam is well tolerated in the recommended doses. The usual side effects are mild and transient gastric, abdominal discomfort, dyspepsia, heartburn, nausea, dizziness, headache, itching, erythema, rash, urticaria, increase in BUN or creatinine, edema and palpitations. In isolated cases GI-perforation, asthma, angioedema and elevated blood pressure may occur.

Precautions

Caution should be exercised in patients have symptoms of gastrointestinal diseases. If peptic ulceration or gastrointestinal bleeding occurs, Tenoxicam should be immediately withdrawn. It is necessary to adequately monitor the patient with increased risk of developing renal failure, impaired renal function in diabetics, hepatic cirrhosis and congestive heart failure. Patients having coagulation disorders or receiving therapy that interferes with haemostasis should, however, be carefully observed when treated with Tenoxicam. In women who have difficulty conceiving or are undergoing investigation of infertility, withdrawal of Tenoxicam should be considered.

Drug Interaction

Salicylates increase the clearance and volume of distribution of Tenoxicam by displacing it from protein binding sites. Concurrent treatment with salicylate or other NSAIDs is not recommended because of increased risk of undesirable reactions. Co-administration of Tenoxicam and methotrexate has been associated with reduced renal tubular secretion of methotrexate. As with NSAIDs in general, Tenoxicam should not be administered concurrently with potassium sparing diuretics. Tenoxicam might attenuate the antihypertensive effects of adrenergic blockers and ACE-inhibitors. It may also enhance the effect of antidiabetic drug (sulphonylurea group).

Over dosage

Although there is no experience of acute overdosage with Tenoxicam. Overdose should be countered by reducing absorption (eg. gastrolavage and charcoal) and speed up elimination (eg. cholestyramine).

Pharmaceutical Precautions

Store in cool and dry place, away from children.

Commercial Pack

Mobicam® Tablet: Box contains 30 tablets in 3x10's blister strips. Each tablet contains Tenoxicam BP 20 mg.

Manufactured by

BEXIMCO PHARMACEUTICALS LTD.

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