

Tenoxicam BP

COMPOSITION

Each film-coated tablet contains Tenoxicam BP 20 mg.

PHARMACOLOGY

Enocam (Tenoxicam) is a non steroidal anti inflammatory drug (NSAID) with anti-inflammatory, analgesic, antipyretic properties and it also inhibits platelet aggregation. Tenoxicam inhibits prostaglandin biosynthesis. It is a potent inhibitor of human metalloproteinases (Stromelysin and collagenase), which induce cartilage breakdown. These pharmacological effects explain, at least in part the therapeutic benefit of Enocam in the treatment of painful inflammatory and degenerative disorders of the musculoskeletal system.

INDICATIONS

Enocam (Tenoxicam) is indicated for the symptomatic treatment of the following painful inflammatory and degenerative disorders of the musculoskeletal system: rheumatoid arthritis; osteoarthritis; ankylosing spondylitis; extra-articular disorders, e.g. tendinitis, bursitis, periarthritis of the shoulders (shoulder-hand syndrome) or hips, strains and sprain. It is also indicated for postoperative pain, acute gout and primary dysmenorrhoea.

DOSAGE AND ADMINISTRATION

Route of administration: Oral.

For all indications (except primary dysmenorrhoea, post-operative pain and acute gout) the usual recommended dose is 20 mg once daily. Enocam should be taken at the same time of day. In case of rheumatoid arthritis, Enocam should be taken at night to relieve the morning stiffness.

The recommended dose for primary dysmenorrhoea 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 patients under 16 years of age.

OR AS DIRECTED BY THE PHYSICIAN.

CONTRAINDICATIONS

Tenoxicam must not be administered to patients: known to be hypersensitive to the drug in whom salicylates or other non-steroidal anti-inflammatory drugs (NSAIDs) induce symptoms of asthma, rhinitis or urticaria; suffering or having suffered from disease of the GI tract such as gastritis, gastric and duodenal ulcer.

WARNING & PRECAUTIONS

NSAIDs inhibit renal prostaglandin synthesis and consequently may have an undesirable effect on renal hemodynamics and on salt and water balance. It is necessary to adequately monitor the patient with a special emphasis on cardiac and renal function (BUN, creatinine, development of edema, weight gain, etc.) when giving Tenoxicam to patients with conditions that could increase their risk of developing renal failure, such as pre-existing renal disease, impaired renal function in diabetics, hepatic cirrhosis, congestive heart failure, volume depletion or concomitant treatment with potentially nephrotoxic drugs, diuretics and corticosteroids. Tenoxicam inhibits platelet aggregation and may affect hemostasis. Tenoxicam has no significant influence on blood coagulation factors, coagulation time, prothrombin time or activated thromboplastin time.

SIDE EFFECTS

Common side effects: 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 case GI-perforation, asthma, angioedema and elevated blood pressure may occur.

Rare side effects:

USE IN PREGNANCY & LACTATION

NSAIDs have an inhibitory effect on prostaglandin synthesis and, when given during late pregnancy, may cause closure of the fetal ductus arteriosus, prolong labor and delay parturition. Treatment during the third trimester of pregnancy should be avoided. Based on findings from single-dose, administration, a very small amount (approximately 0.2%) of Tenoxicam passes into breast milk. There is no evidence of adverse reactions in breast-fed infants of mothers taking Tenoxicam.

USE IN CHILDREN & ADOLESCENTS

DRUG INTERACTIONS

As in the case of other NSAIDs, salicylate displaces Tenoxicam from protein-binding sites and increase clearance and volume of distribution of Tenoxicam. Concurrent treatment with salicylate or other NSAIDs should be avoided because of increased risk of gastrointestinal undesirable reactions. The co-administration of some NSAIDs and Methotrexate has been associated with reduced renal tubular secretion of methotrexate, higher plasma concentrations of Methotrexate, and severe methotrexate toxicity. As with NSAIDs in general, Tenoxicam should not be administered concurrently with K-sparing diuretics. Tenoxicam might attenuate the Antihypertensive effects of α -adrenergic blockers and ACE-inhibitor. It may also enhance the effect of antidiabetic drug (Sulphonylurea group). No clinically significant interaction between Tenoxicam and Furosemide was noted, but Tenoxicam attenuates the blood pressure-lowering effect of hydrochlorothiazide.

OVERDOSE

STORAGE

Store below 300 C temperature & dry place, protected from light.
Keep all medicines out of reach of children.

PACKING

Each box contains 3 x 10 tablets in blister strips.

* Further information is available on request.



Manufactured by:

The **ACME** *Laboratories Ltd.*

Dhamrai, Dhaka, Bangladesh

For Health, Vigour and Happiness

70