Tenoflex
Tenoxicam

COMPOSITION
Tenoflex Tablet: Each film coated tablet contains Tenoxicam BP 20 mg.

PHARMACOLOGICAL INFORMATION

Mechanism of action
Tenoflex (Tenoxicam) is a nonsteroidal anti-inflammatory drug (NSAID) with anti-inflammatory, analgesic and antipyretic properties and it also inhibits platelet aggregation. It inhibits the activity of enzyme cyclo-oxygenase, resulting in decreased formation of precursors of prostaglandins and thromboxanes from arachidonic acid. Tenoxicam is a potent in-vitro inhibitor of human metalloproteinases (stromelysin and collagenase), which induce cartilage breakdown.

PHARMACOKINETIC PROPERTIES

Absorption
Tenoxicam is well absorbed after oral administration. After oral administration Peak plasma concentration reaches within two hours in fasting stage. Presence of food delays the absorption of Tenoxicam. The average concentration at steady state is 11 mg/L when Tenoxicam is given at oral doses of 20 mg once daily and this does not change even on treatment for up to four years.

Distribution
During the first two hours following intravenous administration of Tenoxicam, plasma levels of the medicine decline rapidly. The mean volume of distribution at steady state is 10 to 12 L. Tenoxicam is over 98.5% bound to plasma proteins and penetrates synovial fluid. Peak concentrations are reached later than in plasma.

Elimination
The elimination half-life is about 60 to 75 hours. Tenoxicam is completely metabolised to inactive metabolites. About 66% of the dose is excreted through the renal route and about 17% of the dose through the biliary/faecal route.

INDICATIONS
Tenoflex (Tenoxicam) is used to relieve inflammation, swelling, stiffness and pain associated with

- Rheumatoid arthritis
- Osteoarthritis
- Ankylosing spondylitis
- Acute gout
- Tendinitis
- Bursitis and
- Periarthritis of the shoulders or hips

DOSAGE & ADMINISTRATION
Standard dosage: For all indications except acute gout, a daily dosage of 20 mg should be given at the same time of day.

Acute musculoskeletal disorder: 20 mg daily for 7 days, maximum duration of treatment 14 days.

Acute gout: The recommended dose for acute attacks of gout is 40 mg once daily for two days followed by 20 mg once daily for a further five days.

Long-term use: For patients needing long-term treatment a reduction to a daily oral dose of 10 mg may be tried for maintenance.

USE IN PREGNANCY & LACTATION
Treatment during the third trimester of pregnancy should be avoided. A very small amount (approximately 0.2%) of Tenoxicam passes into breast milk. Lactation should be avoided or drug should be discontinued.

SIDE EFFECTS

Hypersensitivity reactions: Angioedema, bronchospastic allergic reactions.

Dermatologic Effects: Allergic dermatitis (itching, skin rash, hives etc.)

Gastrointestinal Effects: Glossitis, decreased appetite, abdominal distension, dysphagia, oesophagitis, gastritis, gastrointestinal bleeding, nausea, vomiting.

Hematologic Effects: Anaemia, leucopenia, thrombocytopenia, agranulocytosis, neutropenia.

Cardiovascular Effects: Fast heart beat, flushing or hot flushes, increased sweating, pounding heart beat, unexplained nose bleeding, pulmonary edema, increased blood pressure.

Central Nervous System Effects: Headache, dizziness, light headedness or vertigo, nervousness or irritability, mental confusion, depression, tinnitus, insomnia, fatigue.

Genitourinary Effects: Cystitis, hematuria, dysuria, incontinence, proteinuria, polyuria, renal impairment or failure.

Ophthalmic Effects: Conjunctivitis, blurred or double vision, changes in visual colour perception and toxic amblyopia.

Other side-effects: Abnormalities in liver function tests.

DRUG INTERACTIONS

Paracetamol: Prolonged concurrent use with Tenoxicam may increase the risk of adverse renal effects.

Anticoagulants or Thrombolytic Agents: Inhibition of platelet aggregation by Tenoxicam and possibility of NSAID induced gastrointestinal ulceration or bleeding may be hazardous to patients receiving anticoagulant thrombolytic therapy.

Oral antidiabetic agents and Insulin: Tenoxicam may increase the hypoglycaemic effects of these agents.

NSAIDs: Concurrent use of Tenoxicam and another NSAIDs may increase the risk of gastrointestinal toxicity including ulceration or hemorrhage without providing additional symptomatic relief.

Cefamandole, Cefoperazone, Cefotetan, Plicamycin, Valproic acid: These medicines are likely to cause hypoprothombinemia. Thus concurrent use with Tenoxicam may increase risk of bleeding because of interferences with platelet function and/or the potential occurence of NSAID-induced gastro-intestinal ulceration or hemorrhage.

Tenoxicam should not be administered concurrently with potassium-sparing diuretics, lithium or Methotrexate.

PRECAUTIONS

General: Tenoxicam should not be given to patients with active peptic ulcer disease or gastrointestinal bleeding. However, if treatment with this medication is unavoidable, an antiulcer regimen should be administered concurrently. Tenoxicam may mask the usual signs of infection. It should be given with care to the elderly, patients with asthma or bronchospasm, bleeding disorders, cardiovascular disease and in liver or renal failure. Care is also necessary in patients receiving coumarin anticoagulants. Tenoxicam should be discontinued in patients who experience blurred or diminished vision or changes in colour vision.

Geriatrics: The risk of hyperkalemia may be increased in elderly patients.

Dental: Tenoxicam may cause soreness, irritation or ulceration of the oral mucosa.

CONTRAINDICATIONS

- Hypersensitivity to any of the ingredients.
- History of severe allergic reactions (anaphylaxis or angioedema induced by aspirin or other NSAIDs)
- Aspirin induced nasal polyps associated with bronchospasm.
- The safety in pregnancy and lactation has not been established.
- No information is available on the relationship of age to the effects of Tenoxicam in paediatric patients. Safety, efficacy and appropriate dosages have not been established.

OVERDOSE

Gastrointestinal bleeding may occur. Hypertension, acute renal failure, respiratory depression and coma may occur after the ingestion of NSAIDs but are rare. Anaphylactoid reactions have been reported with NSAIDs at therapeutic doses, and may occur following an overdose.

Treatment: Patients should be managed by symptomatic and supportive care following NSAIDs overdose. There are no specific antidotes. Dialysis does not significantly clear NSAIDs from the blood stream.

PHARMACEUTICAL INFORMATION

Storage Conditions

Store in a cool and dry place, away from light. Keep out of the reach of children.

Presentation & Packaging

Tenoflex Tablet: Each commercial box contains 30 tablets in blister pack.

Manufactured By
BEACON®
Pharmaceuticals PLC
Bhaluka, Mymensingh, Bangladesh

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