Texicam
Tenoxicam

Tablet

Composition: Texicam Tablet: Each enteric coated tablet contains Tenoxicam BP 20 mg

Description: Tenoxicam is a non-steroidal anti-inflammatory drug (NSAID) which has marked anti-inflammatory and analgesic activity and some antipyretic activity. As with other non-steroidal anti-inflammatory drugs, the precise mode of action is unknown, though it is probably multifactorial, involving inhibition of prostaglandin biosynthesis and reduction of leucocyte accumulation at the inflammatory site.

Indications and Uses: Tenoxicam is indicated for the relief of pain and inflammation in osteoarthritis and rheumatoid arthritis. It is also indicated for the short term management of acute musculoskeletal disorders including strains, sprains and other soft-tissue injuries.

Dosage and Administration: ***Adults:*** A single daily dose of 20 mg Tenoxicam should be taken orally, at the same time each day. Tenoxicam Tablets are for oral administration with water or other fluid. Higher doses should be avoided as they do not usually achieve significantly greater therapeutic effect but may be associated with a higher risk of adverse events. In acute musculoskeletal disorders treatment should not normally be required for more than 7 days, but in severe cases it may be continued up to a maximum of 14 days.

Elderly: As with other non-steroidal anti-inflammatory drugs, Tenoxicam should be used with special caution in elderly patients since they may be less able to tolerate than younger patients. They are also more likely to be receiving concomitant medication or to have impaired hepatic, renal or cardiovascular function. The lowest dose should be used in elderly patients and the patient should be monitored for GI bleeding for 4 weeks following initiation of NSAID therapy.

Children: There are insufficient data to make a recommendation for administration of Tenoxicam to children.

Contraindications: 1. Active peptic ulceration and a past history of peptic ulceration, gastro-intestinal bleeding (melaena, haematemesis) or severe gastritis. 2. Hypersensitivity to Tenoxicam. Tenoxicam should also be avoided in cases where the patient has suffered a hypersensitivity reaction (symptoms of asthma, rhinitis, angioedema or urticaria) to other non-steroidal anti-inflammatory drugs, including aspirin, as the potential exists for cross-sensitivity to Tenoxicam. 3. Severe heart failure Precautions Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms NSAIDs should only be given with care to patients with a history of gastrointestinal disease. Any patient being treated with Tenoxicam who presents with symptoms of gastro-intestinal disease should be closely monitored. If peptic ulceration or gastro-intestinal bleeding occurs, Tenoxicam should be withdrawn immediately.

Pregnancy and Lactation: The safety of Tenoxicam during pregnancy and lactation has not been established and the drug should therefore not be given in these conditions. Congenital abnormalities have been reported in association with ibuprofen administration in man; however, these are low in frequency and do not appear to follow any discernible pattern. Although no teratogenic effects were seen in animal studies, Tenoxicam, like other non-steroidal anti-inflammatory drugs, is associated with prolonged and delayed parturition and an adverse influence on neonatal viability when administered to animals in late pregnancy. Non-steroidal anti-inflammatory agents are also known to induce closure of the ductus arteriosus in infants, therefore use in late pregnancy should be particularly avoided. In the limited studies available so far, ibuprofen appears in the breast milk in very low concentrations and is unlikely to adversely affect the breast fed infant. No information is available on penetration of Tenoxicam into milk in humans; animal studies indicate that significant levels may be achieved.

Side Effects: For most patients, any side-effects are transient and resolve without discontinuation of treatment. The most common side-effects relate to the gastro-intestinal tract. They include dyspepsia, nausea, abdominal pain and discomfort, constipation, diarrhoea, flatulence, indigestion, epigastric distress, stomatitis and anorexia. As with other non-steroidal anti-inflammatory drugs, there is a risk of peptic ulceration and gastro-intestinal bleeding, both of which have been reported with Tenoxicam. Should this occur, Tenoxicam is to be discontinued immediately and appropriate treatment instituted. As with other non-steroidal anti-inflammatory drugs, peripheral oedema of mild or moderate degree and without clinical sequelae occurred in a small proportion of patients and the possibility of precipitating congestive cardiac failure in elderly patients or those with compromised cardiac function should therefore be borne in mind. Clinical trial and epidemiological data suggest that use of some NSAIDs (particularly at high doses and in long term treatment) may be associated with an increased risk of arterial thrombotic events (for example myocardial infarction or stroke). Oedema, hypertension and cardiac failure have been reported in association with NSAID treatment. Central nervous system reactions of headache and dizziness have been reported in a small number of patients. Somnolence, insomnia, depression, nervousness, dream abnormalities, mental confusion, paraesthesias and vertigo have been reported rarely. Hypersensitivity reactions have been reported following treatment with NSAIDs, these include: a) Non specific allergic reactions and anaphylaxis.

Drug Interactions: Antacids may reduce the rate, but not the extent, of absorption of Tenoxicam. The differences are not likely to be of clinical significance. No interaction has been found with concomitantly administered cimetidine. In healthy subjects no clinically relevant interaction between Tenoxicam and low molecular weight heparin has been observed. Tenoxicam is highly bound to serum albumin, and can, as with all NSAIDs, enhance the anticoagulant effect of warfarin and other anticoagulants. Close monitoring of the effects of anticoagulants and oral glycaemic agents is advised, especially during the initial stages of treatment with Tenoxicam. No interaction with digoxin has been observed. Tenoxicam and other NSAIDs can reduce the effects of anti-hypertensive drugs. NSAIDs may exacerbate cardiac failure, reduce GFR and increase plasma cardiac glycoside levels when co-administered with cardiac glycosides. As with all NSAIDs caution is advised when cyclosporin is co-administered because of the increased risk of nephrotoxicity. Concomitant use of two or more NSAIDs should be avoided. Patients taking quinolones may have an increased risk of developing convulsions.

Packaging: Texicam Tablet: Each Box containing 2x10 tablets in blister strips.

Apex pharma®

Manufactured by
Apex Pharma Ltd.
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