Tenoxicam tablets film-coated

Drug description :
Each film-coated tablet contains 20mg Tenoxicam

Presentation :
Film-coated tablet. Round, yellowish film-coated tablet.

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

Adult Dosage :
The tablets are for oral use and should be taken with water or other fluid, preferably with or after food.

Adults:
The recommended dosage is a single daily dose of 20mg taken at the same time each day.

As there is no significantly greater therapeutic effect at higher doses, and higher doses may result in an increase of adverse events, oral doses greater than recommended should be avoided.

Tenoxicam 20 mg Tablets should only be used for up to a maximum of 2 weeks in cases of severe acute musculoskeletal disorders. Usually treatment of up to 7 days is sufficient.

Use in renal and hepatic insufficiency:
In renal impairment, the normal dosage with careful monitoring is recommended for patients with a creatinine clearance of greater than 25ml/min. There are insufficient data to make dosage recommendations for patients with a creatinine clearance of less than 25ml/min .

There are insufficient data to make dosage recommendations for Tenoxicam in patients with pre-existing hepatic impairment.

Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms

Child Dosage :
Tenoxicam 20mg Tablets should not be used in children until sufficient data become available.

Elderly Dosage :
The elderly are at increased risk of the serious consequences of adverse reactions. If an NSAID is considered necessary, the lowest dose should be used and the patient should be monitored for GI bleeding for 4 weeks following initiation of therapy.

Contra Indications :
Tenoxicam 20 mg Tablets is contra-indicated in:-

- Severe heart failure
- Active peptic ulceration.
- A previous history of peptic ulceration, severe gastritis, or gastrointestinal bleeding.
- Patients with a known hypersensitivity to ibuprofen, aspirin or other non-steroidal anti-inflammatory drugs (symptoms of asthma, rhinitis, angioedema or urticaria).
- Previous known hypersensitivity to tenoxicam or any of the excipients contained in Tenoxicam 20 mg Tablets

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Special 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.

Patients showing signs of gastrointestinal disease during treatment with Tenoxicam, should be carefully monitored and if peptic ulceration or gastrointestinal bleeding occurs, the drug should be withdrawn immediately.

Cardiovascular and cerebrovascular effects

Appropriate monitoring and advice are required for patients with a history of hypertension and/or mild to moderate congestive heart failure as fluid retention and oedema have been reported in association with NSAID therapy.

Clinical trial and epidemiological data suggest that use of some NSAIDs (particularly at high doses and in long term treatment) may be associated with a small increased risk of arterial thrombotic events (for example myocardial infarction or stroke). There are insufficient data to exclude such a risk for Tenoxicam.

Patients with uncontrolled hypertension, congestive heart failure, established ischaemic heart disease, peripheral arterial disease, and/or cerebrovascular disease should only be treated with Tenoxicam after careful consideration. Similar consideration should be made before initiating longer-term treatment of patients with risk factors for cardiovascular disease (e.g. hypertension, hyperlipidaemia, diabetes mellitus, smoking).

In rare cases, NSAIDs may cause interstitial nephritis, glomerulonephritis, papillary necrosis and the nephrotic syndrome. Such agents inhibit the synthesis of renal prostaglandin which plays a supportive role in the maintenance of renal perfusion in patients whose renal blood flow and blood volume are decreased. Administration of a NSAID in these patients may precipitate overt renal decompensation, which returns to the pre-treatment state upon withdrawal of the drug.

Patients at greatest risk of such a reaction are those with pre-existing renal disease (including diabetics with impaired renal function), nephrotic syndrome, volume depletion, hepatic disease, congestive cardiac failure and those patients receiving concomitant therapy with diuretics or potentially nephrotoxic drugs. Such patients should have their renal, hepatic and cardiac functions carefully monitored, and the dose should be kept as low as possible in patients with renal, hepatic or cardiac impairment. NSAIDs should be given with care to patients with a history of heart failure or hypertension since oedema has been reported in association with NSAID administration.

Caution is required if administered to patients suffering from, or with a previous history of, bronchial asthma since NSAIDs have been reported to cause bronchospasm in such patients.

Occasional elevations of serum transaminases or other indicators of liver function have been reported. The reports in most cases, have been small and transient increases above the normal range. If the abnormality is significant or persistent, Tenoxicam should be stopped and follow-up tests carried out. Particular care is required in patients with pre-existing hepatic disease.

Tenoxicam reduces platelet aggregation and may prolong bleeding time. Care is therefore required in patients undergoing major surgery and in patients whose bleeding time needs to be determined.

The elderly are at increased risk of the serious consequences of adverse reactions. Care should be taken to regularly monitor the patients to detect possible interactions with concomitant therapy and to review renal, hepatic and cardiovascular function which may be potentially influenced by NSAIDs.

Minor and serious ocular effects have been reported rarely in patients taking NSAIDs; ophthalmic evaluation is recommended for patients who develop visual disturbances during treatment with Tenoxicam.

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According to the Indian Trade Mark the company owns about 450 brands and 4600 generic manufacturing permissions in India. According to the export data analysis the company was the largest exporter of generic medicines to the Europe and Middle East countries. www.tajpharma.com

The company medicines are present in France, Georgia, Egypt and CIF countries.

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