Information for Health Professionals

Tenoxicam 20 mg Lyophilisate for Solution for Injection

Anti-Inflammatory

Indications

IM, IV tenoxicam is for patients considered unable to take oral tenoxicam for the relief of pain and inflammation in osteoarthritis and rheumatoid arthritis and for the short-term management of acute musculoskeletal disorders including strains, sprains and other soft-tissue injuries.

Dosage and administration

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

Adults

Tenoxicam Lyophilisate should be given IV or IM. A single daily dose of 20 mg for one to two days initially to be continued with the oral form, with administration at the same time each day. The lyophilisate should be dissolved in 2 ml of sterile water for injections and the reconstituted solution should be used immediately.

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 Lyophilisate should be used with special caution in elderly patients. The elderly are at increased risk of serious consequences of adverse reactions. They are also more likely to be receiving concomitant medication or to have impaired hepatic, renal or cardiovascular function. If an NSAID is considered necessary, the lowest effective dose should be used and for the shortest possible duration. The patient should be monitored regularly for GI bleeding during NSAID therapy.

Children

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

Use in renal and hepatic insufficiency

Creatinine clearence	Dosage regimen
Greater than 25ml/min:	Usual dosage but monitor patients carefully (see Precautions)
Less than 25ml/min:	Insufficient data to make dosage recommendations

Because of the high plasma protein-binding of tenoxicam, caution is required when plasma albumin concentrations are markedly reduced (e.g. in nephrotic syndrome) or when bilirubin concentrations are high.

There is insufficient information to make dosage recommendations for Tenoxicam Lyophilisate in patients with existing hepatic impairment.

Properties

Tenoxicam Lyophilisate is a non-steroidal anti-inflammatory drug which has marked anti-inflammatory and analgesic activity and some antipyretic activity. Tenoxicam Lyophilisate contains the substance with the approved name tenoxicam. It is chemically described as 4-hydroxy-2-methyl-*N*-(pyridin-2-yl)-2*H*-thieno-[2,3-*e*]1,2-thiazine-3-carboxamide 1, 1-dioxide. 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.

Pharmacokinetics

Tenoxicam Lyophilisate is long-acting; a single daily dose is effective.

Tenoxicam penetrates well into synovial fluid to give concentrations approximately half those in plasma. The mean plasma elimination half-life is approximately 72 hours.

Following intravenous administration of 20 mg tenoxicam, plasma levels of the drug decline rapidly during the first two hours mainly due to distribution processes.

Following intramuscular injection levels at or above 90% of the maximally achieved concentrations are reached as early as 15 minutes after a dose.

With the recommended dosage regimen of 20 mg once daily, steady-state plasma concentrations are reached within 10-15 days, with no unexpected accumulation.

Tenoxicam is strongly bound to plasma proteins.

Tenoxicam is cleared from the body almost exclusively by metabolism. Approximately two-thirds of the administered dose is excreted in the urine, mainly as the pharmacologically inactive 5-hydroxypyridyl metabolite, and the remainder in the bile, much of it as glucuronide conjugates of hydroxyl-metabolites.

No age-specific changes in the pharmacokinetics of tenoxicam have been found although inter-individual variation tends to be higher in elderly persons.

Use in Pregnancy and Lactation

The safety of Tenoxicam Lyophilisate 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 NSAID administration in man; however, these are low in frequency and do not appear to follow any discernible pattern. In view of the known effects of NSAIDs on the foetal cardiovascular system (risk of closure of the ductus arteriosus), use in the last trimester of pregnancy is contraindicated.

The onset of labour may be delayed and the duration increased with an increased bleeding tendency in both mother and child. NSAIDs should not be used during the first two trimesters of pregnancy or labour unless the potential benefit to the patients outweighs the potential risk to the foetus.

In the limited studies available so far, NSAIDs can appear in the breast milk in very low concentrations. NSAIDs should, if possible, be avoided when breastfeeding.

No information is available on penetration of Tenoxicam Lyophilisate into milk in humans; animal studies indicate that significant levels may be achieved.

Contra-indications

1. Active, or history of recurrent peptic ulcer/haemorrhage (two or more distinct episodes of proven ulceration or bleeding), ulcerative colitis, Crohn's disease, severe gastritis, or history of gastrointestinal bleeding or perforation, related to previous NSAID therapy.
2. Hypersensitivity to tenoxicam or to any of the excipients. Tenoxicam Lyophilisate is also contraindicated in patients who have previously shown hypersensitivity reactions (symptoms of asthma, rhinitis, angioedema or urticaria) to other NSAIDs, including ibuprofen and aspirin, as the potential exists for cross-sensitivity to tenoxicam.
3. Severe heart failure, hepatic failure and renal failure.
4. Last trimester of pregnancy.

Precautions

The use of Tenoxicam Lyophilisate with concomitant NSAIDs including COX-2 selective inhibitors should be avoided. Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms

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).

Cardiovascular, renal and hepatic impairment: The administration of an NSAID may cause a dose dependent reduction in prostaglandin formation and precipitate renal failure. Patients at a greater risk of this reaction are those taking diuretics and the elderly. Renal function should be monitored in these patients.

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

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. In these patients, administration of an NSAID 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, cardiac impairment and those patients receiving concomitant therapy with diuretics or potentially nephrotoxic drugs. Such patients should have their renal, hepatic and cardiac functions carefully monitored. The dose should be kept as low as possible in these patients. NSAIDs should be given with care to patients with a history of heart failure or hypertension since oedema has been reported in association with ibuprofen administration.

Dermatological: Serious skin reactions, some of them fatal, including exfoliative dermatitis, Stevens-Johnson syndrome, and toxic epidermal necrolysis, have been reported very rarely in association with the use of NSAIDs. Patients appear to be at highest risk for these reactions early in the course of therapy: the onset of the reaction occurring in the majority of cases within the first month of treatment. Tenoxicam Lyophilisate should be discontinued at the first appearance of skin rash, mucosal lesions, or any other sign of hypersensitivity.

Elderly: The elderly have an increased frequency of adverse reactions to NSAIDs especially GI bleeding and perforation which may be fatal. Particular care should be taken to regularly monitor elderly patients to detect possible interactions with concomitant therapy and to review renal, hepatic and cardiovascular function which may be potentially influenced by NSAIDs.

Impaired female fertility: The use of Tenoxicam Lyophilisate may impair female fertility and is not recommended in women attempting to conceive. In women who have difficulties conceiving or who are undergoing investigation of fertility, withdrawal of Tenoxicam Lyophilisate should be considered.

Gastrointestinal bleeding, ulceration and perforation: NSAIDs should only be given with care to patients with a history of gastrointestinal disease. GI bleeding, ulceration or perforation, which can be fatal, has been reported with all NSAIDs at any time during treatment, with or without warning symptoms or a previous history of serious GI events.

The risk of GI bleeding, ulceration or perforation is higher with increasing NSAID doses, in patients with a history of ulcer, particularly if complicated with haemorrhage or perforation, and in the elderly. These patients should commence treatment on the lowest dose available. Combination therapy with protective agents (e.g. misoprostol or proton pump inhibitors) should be considered for these patients, and also for patients requiring concomitant low dose aspirin, or other drugs likely to increase gastrointestinal risk.

Patients with a history of GI toxicity, particularly the elderly, should report any unusual abdominal symptoms (especially GI bleeding) particularly in the initial stages of treatment.

Caution should be advised in patients receiving concomitant medication which could increase the risk of ulceration or bleeding, such as oral corticosteroids, anticoagulants such as warfarin, selective serotonin-reuptake inhibitors or anti-platelet agents such as aspirin.

Any patient being treated with Tenoxicam Lyophilisate who presents with symptoms of gastrointestinal disease should be closely monitored. If peptic ulceration or GI bleeding occurs, Tenoxicam Lyophilisate should be withdrawn immediately.

NSAIDs should be given with care to patients with a history of gastrointestinal disease (ulcerative colitis, Crohn's disease) as these conditions may be exacerbated.

Haematological effect: Tenoxicam reduces platelet aggregation and may prolong bleeding time. This should be borne in mind for patients who undergo major surgery (e.g. joint replacement) and when bleeding time needs to be determined.

Ophthalmic effect: Adverse eye findings have been reported with NSAIDs, therefore it is recommended that patients who develop visual disturbances during treatment with Tenoxicam Lyophilisate have ophthalmic evaluation.

Respiratory disorders: 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.

SLE and mixed connective tissue disease: In patients with systemic lupus erythematosus (SLE) and mixed connective tissue disorders there may be an increased risk of aseptic meningitis.

Drug interactions

Anticoagulants: In healthy subjects no clinically relevant interaction between Tenoxicam Lyophilisate 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 Lyophilisate.

Antiplatelet agents and selective serotonin reuptake inhibitors (SSRIs): Increased risk of gastrointestinal bleeding.

Antihypertensives: Tenoxicam and other NSAIDs can reduce the effects of anti-hypertensive drugs.

Cardiac glycosides: NSAIDs may exacerbate cardiac failure, reduce GFR and increase plasma cardiac glycoside levels when co-administered with cardiac glycosides.

Ciclosporin: As with all NSAIDs caution is advised when ciclosporin is co-administered because of the increased risk of nephrotoxicity.

Cimetidine: No interaction has been found with concomitantly administered cimetidine.

Corticosteroids: As with all NSAIDs, caution should be taken when co-administering corticosteroids because of the increased risk of GI ulceration or bleeding.

Diuretics: Reduced diuretic effect. NSAIDs may cause sodium, potassium and fluid retention and may interfere with the natriuretic action of diuretic agents, which can increase the risk of nephrotoxicity of NSAIDs. These properties should be kept in mind when treating patients with compromised cardiac function or hypertension since they may be responsible for a worsening of those conditions.

Lithium: NSAIDs have been reported to decrease elimination of lithium. If tenoxicam is prescribed for a patient receiving lithium therapy, the frequency of lithium monitoring should be increased, the patient warned to maintain fluid intake and to be aware of symptoms of lithium intoxication.

Methotrexate: Caution is advised where methotrexate is given concurrently because of possible enhancement of its toxicity, since NSAIDs have been reported to decrease elimination of methotrexate.

Mifepristone: NSAIDs should not be used for 8 - 12 days after mifepristone administration as NSAIDs can reduce the effects of mifepristone.

NSAIDs, COX-2 Selective Inhibitors, Salicylates: Avoid concomitant use of two or more NSAIDs (including aspirin) as this may increase the risk of adverse effects.

Salicylates can displace tenoxicam from protein-binding sites and so increase the clearance and volume of distribution of Tenoxicam Lyophilisate. Concurrent treatment with salicylates or other NSAIDs should therefore be avoided because of the increased risk of adverse reactions (particularly gastro-intestinal).

Penicillamine and parenteral gold: No clinically relevant interaction was found in small numbers of patients receiving treatment with penicillamine or parenteral gold.

Quinolones: Animal data indicate that NSAIDs can increase the risk of convulsions associated with quinolone antibiotics. Patients taking NSAIDs and quinolones may have an increased risk of developing convulsions.

Tacrolimus: Possible increased risk of nephrotoxicity when NSAIDs are given with tacrolimus.

Zidovudine: Increased risk of haematological toxicity when NSAIDs are given with zidovudine. There is evidence of an increased risk of haemarthroses and haematoma in HIV positive haemophiliacs receiving concurrent treatment with zidovudine and ibuprofen.

Side-effects and adverse reactions

For most patients, any side-effects are transient and resolve without discontinuation of treatment. The most commonly observed adverse events are gastrointestinal in nature.

Cardiovascular and cerebrovascular: Oedema, hypertension, and cardiac failure, have been reported in association with NSAID treatment. Palpitations and dyspnoea have been reported rarely.

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).

Dermatological: Photosensitivity and bullous reactions including Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis (very rare) have been reported.

Eye disorders: Visual distrurbance (such as visual impairment and blurred vision) have been reported with frequency unknown.

Gastrointestinal disorders: The most common side-effects relate to the GI tract. They include dyspepsia, nausea, vomiting, abdominal pain and discomfort, constipation, diarrhoea, flatulence, indigestion, epigastric distress, melaena, haematemesis, ulcerative stomatitis, anorexia, exacerbation of colitis and Crohn's disease.

As with other NSAIDs, there is a risk of peptic ulceration, perforation or GI bleeding, which may be fatal, particularly in the elderly. Less frequently, gastritis has been observed. Pancreatitis has been reported very rare.

Haematological: Decreases in haemoglobin, unrelated to gastro-intestinal bleeding, have occurred. Anaemia, aplastic anaemia, haemolytic anaemia,thrombocytopenia and non-thrombocytopenic purpura, leucopenia, neutropenia and eosinophilia have been reported. Epistaxis has been reported infrequently. Rare cases of agranulocytosis have been reported.

Hepatic: Abnormal liver function. As with most other NSAIDs, changes in various liver function parameters have been observed.

Some patients may develop raised serum transaminase levels during treatment. Although such reactions are rare, if abnormal liver function tests persist or worsen, if clinical signs and symptoms consistent with liver disease develop or if systemic manifestations occur (e.g. eosinophilia, rash), Tenoxicam Lyophilisate should be discontinued. Hepatitis and jaundice have also been reported.

Hypersensitivity: Hypersensitivity reactions have been reported following treatment with NSAIDs, these include:

a) Non specific allergic reactions and anaphylaxis
b) Respiratory tract reactivity comprising asthma, aggravated asthma, bronchospasm or dyspnoea or
c) Assorted skin disorders; incl. rashes of various types. Angioedema, pruritus, and purpura have been reported. Nail disorders, alopecia, erythema, urticaria, and photosensitivity reactions have been reported rarely. As with other NSAIDs, exfoliative and bullous dermatoses, incl. epidermal necrolysis, erythema multiforme and Stevens-Johnson syndrome may develop in rare instances. Vesiculo-bullous reactions and vasculitis have also been reported rarely.

Metabolism: Metabolic abnormalities, such as weight decrease or increase and hyperglycaemia, have occurred rarely.

Nervous system disorders: Malaise and tinnitus may occur.

Other less common reports include: Aseptic meningitis (especially in patients with existing auto-immune disorders, such as systemic lupus erythematosus, mixed connective tissue disease), with symptoms such as stiff neck, headache, nausea, vomiting, fever or disorientation, dizziness, malaise, fatigue and drowsiness.

Headache, insomnia, depression, nervousness dream abnormalities and vertigo have been reported rarely. Somnolence and paraesthesia have been reported with frequency unknown.

Psychiatric disorders: Confusional state and hallucinations have been reported with frequency unknown.

Renal: Nephrotoxicity has been reported in various forms, including interstitial nephritis, nephrotic syndrome and renal failure.

Reversible elevations of blood urea nitrogen and creatinine have been reported.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medical product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

Treatment of overdosage

Symptoms: There is no reported experience of serious overdosage with Tenoxicam Lyophilisate. Symptoms of NSAID overdose include headache, nausea, vomiting, epigastric pain, GI bleeding, rarely diarrhoea, disorientation, excitation, coma, drowsiness, dizziness, tinnitus, fainting, occasionally convulsions. In cases of significant poisoning acute renal failure and liver damage are possible.

Therapeutic measure: Patients should be treated symptomatically as required. Good urine output should be ensured. Renal and liver function should be closely monitored.

Patients should be observed for at least four hours after a potentially toxic dose. Frequent or prolonged convulsions should be treated with intravenous diazepam. Administration of H2 antagonist drugs may be of benefit. Other measures may be indicated by the patient's clinical condition.

Pharmaceutical precautions

Storage: The pack should be stored at a temperature below 30°C.

Legal category: POM

Presentation: Each pack contains 1 colourless glass vial with a bromobutyl rubber stopper and an aluminium tear-off cap, containing 20mg tenoxicam.

Further information Nil.

Product Licence number: PL 17736/0088

Licence holder: Chemidex Pharma Ltd, trading as Essential Generics, 7 Egham Business Village, Crabtree Road, Egham, Surrey, TW20 8RB.

Manufacturer: Laboratorios Alcalá Farma S.L., Carretera M-300, km 29,920, 28802-Alcalá de Henares (Madrid), Spain.

Patient Information Leaflet

Tenoxicam 20 mg Lyophilisate for Solution for Injection

ESSENTIAL GENERICS

Tenoxicam

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Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What this medicine is and what it is used for

Tenoxicam injection contains tenoxicam, which is a non-steroidal anti-inflammatory drug (NSAID).

It helps to relieve pain and inflammation.

The injection will be given to you by a doctor or nurse into your muscles or veins.

Tenoxicam is effective for:

- reducing pain and inflammation in osteoarthritis and rheumatoid arthritis
- treating short-term injuries such as sprains and strains and other soft-tissue injuries
- when oral tablets cannot be taken.

2. Before you use

Do NOT use Tenoxicam injection if you:

- are allergic to tenoxicam, to any other anti-inflammatory medicines (such as aspirin, ibuprofen, celecoxib), or to any of the other ingredients in the product (see Section 6)
- have ever had a stomach or intestinal condition such as peptic ulcer, bleeding in the stomach or severe gastritis
- have an inflammatory bowel disease (e.g. ulcerative colitis, Crohn's disease)
- have severe heart, liver or kidney problems
- are more than 6 months pregnant.

If any of the above apply to you, speak to your doctor or pharmacist.

Take special care with Tenoxicam injection

Before treatment with the injection, tell your doctor if you:

- are taking any other anti-inflammatory medicines (e.g.diclofenac, ibuprofen, prednisolone)
- are taking aspirin or medicines that thin the blood (e.g. warfarin, clopidogrel)
- are taking antidepressants called selective serotonin reuptake inhibitors (SSRIs) (e.g. paroxetine)
- have kidney or liver problems. Your doctor will check your kidney or liver function before and during treatment
- are elderly (see Section 3)
- are trying to become pregnant (see Section on Fertility)
- have stomach or digestive tract problems or if you have ever had an upset stomach after taking pain killers such as aspirin. Bleeding in the stomach or gut can occur in patients using Tenoxicam
- have a connective tissue disorder, e.g. Systemic Lupus Erythematosus (SLE)
- have problems with your vision. Medicines such as tenoxicam may affect your vision
- have asthma, or a history of asthma, as this medicine may cause breathing difficulties
- have a bleeding disorder or are having major surgery. Tenoxicam can affect the clotting of your blood. It can make you bleed more and for longer than usual
- have heart problems, high blood pressure, previous stroke or think that you might be at risk of any of these conditions (e.g. if you have high blood pressure, diabetes, or high cholesterol or are a smoker). Additional monitoring will be carried out by the doctor.

Medicines such as Tenoxicam may be associated with a small increased risk of heart attack or stroke. Any risk is more likely with high doses and prolonged treatment.

Do not exceed the recommended dose or duration of treatment.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, and herbal preparations.

Some medicines may be affected by Tenoxicam or they may affect how well Tenoxicam will work. Tell your doctor or pharmacist if you are taking:

- medicines that can increase a chance of getting ulcers or a bleed in the stomach or gut, such as:
  - corticosteroids used to treat arthritis and inflammation
  - medicines such as anti-platelet agents, used to thin the blood (e.g. warfarin, aspirin, clopidogrel)
  - antidepressants called selective serotonin reuptake inhibitors (SSRIs) (e.g. paroxetine)
  - any other anti-inflammatory medicines (e.g. NSAIDs, diclofenac, celecoxib)
- medicines used for high blood pressure (e.g. atenolol, ramipril, valsartan)
- diuretics (water tablets)
- heart medicines (e.g. digoxin, sotalol, diltiazem)
- medicines which suppress the immune system (e.g. ciclosporin, tacrolimus, methotrexate)
- lithium, a medicine used to treat mood swings and some types of depression
- a medicine usually prescribed through hospitals, called mifepristone (taken within the last 12 days)
- quinolone antibiotics (antibiotics used to treat infections)
- zidovudine, a medicine used for HIV.

Blood tests

Your doctor may test your blood during treatment.

Pregnancy and breast-feeding

Pregnancy:
Tenoxicam will be passed to your unborn baby. It is not known how much it will affect your unborn baby in the first 6 months of pregnancy.

DO NOT use Tenoxicam injection in the last 3 months) of pregnancy as it may delay the onset of labour and prolong its duration. It may also increase the likelihood of bleeding in the mother and in the baby.

If you need to use Tenoxicam, your doctor can help you decide whether or not to take it during the first 6 months of pregnancy.

Breast-feeding:
Tenoxicam passes into breast milk and can affect the baby. **You should not** use Tenoxicam injection while breast-feeding unless advised by your doctor.

Fertility:
DO NOT use Tenoxicam injection if you are trying to become pregnant as it may make it more difficult to get pregnant. You should inform your doctor if you are planning to become pregnant or if you have problems becoming pregnant.

Ask your doctor for advice before taking any medicine.

Driving and using machines

Tenoxicam may cause dizziness, head-spins, blurred vision and drowsiness. If any of these occur do not drive, use machinery, or perform any tasks that may require you to be alert.

3. How to use

You will most likely receive Tenoxicam injection from a doctor or nurse. Your doctor will have decided what dose is right for you and may suggest a different dose to the usual dose shown below. You should check with your doctor or pharmacist if you are not sure.

- Your doctor or nurse will inject Tenoxicam into your muscles or veins.

Doses

Adults: the usual dose is 20 mg (one injection)for 1 or 2 days, followed by oral tablets taken at the same time each day.

The elderly: your doctor will decide your dose,it will usually be lower than that for other adults.While you are treated with Tenoxicam your doctor will want to see you to check you are on the right dose for you and look for any side effects.This is particularly important if you are elderly. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment.

Children: this injection is **NOT** suitable for children.

The normal length of treatment for:

- pain and inflammation in osteoarthritis and rheumatoid arthritis is 1 to 2 days
- acute musculoskeletal disorders, (such as strains and sprains) is 7 days but in severe cases you may be given Tenoxicam for up to 14 days.

If you use more than you should

Having too much Tenoxicam is unlikely as the injection will be given to you by a doctor or nurse. However, if you are given too much Tenoxicam, you may experience headache, nausea (feeling sick), vomiting and stomach pain. Ask your doctor or nurse if you have any concerns.

If you forget to use

If you think you have missed an injection, speak to your doctor or nurse.

If you have any further questions on the use of this product, ask your doctor or nurse, or your pharmacist.

4. Possible side effects

Like all medicines, Tenoxicam can cause side effects, although not everybody gets them. Do not be alarmed by this list of possible side effects. You may not experience any of them.

Tell you doctor or nurse immediately if you have any of the following **allergic reactions:**

- difficulty breathing or swallowing, swelling of the face, lips, tongue or throat
- severe itching of the skin, with a red rash or raised lumps
- blistering of the mouth, eyes, or genital region, patchy areas of rash, peeling skin

or any of the following **reactions:**

- passing blood in your stools(faeces/motions)
- passing black tarry stools
- vomiting any blood or dark particles that look like coffee grounds.

STOP using Tenoxicam and **seek immediate medical attention** if you have any of the following symptoms:

- indigestion or heartburn, abdominal pain (pain in your stomach) or other abnormal stomach symptoms, nausea (feeling sick), vomiting
- any unusual bruising or bleeding, for example nose-bleeds, pinpoint red spots on the skin, unusual purple bruise like rash on the skin or in the mouth
- signs of anaemia such as feeling tired, breathless, and looking pale
- fever, sore throat, mouth ulcers, repeated infections or infections that will not go away. This may be due to a low level of white blood cells
- sudden headache, stiff neck, fever, sensitivity to bright light, drowsiness and muscle pain, with or without a rash
- fever, rash, nausea, aches and pains, passing more or less urine than usual, passing red urine or passing urine at night. This may be due to changes in your kidneys
- pain behind the ribs radiating towards the back, often worse when lying down, nausea, vomiting, fever. This may be due to inflammation of your pancreas
- yellowing of your skin or eyes, pale faeces and dark urine, unexplained persistent nausea, stomach problems, loss of appetite or unusual tiredness. This may be due to changes in your liver.

Tell your doctor if you get any of the following side effects:

- swelling of the hands and feet (around the ankles)
- a collection of symptoms including thirst, frequent urination, tiredness, and increased susceptibility to infections, such as thrush. This may be due to too much glucose in the body. Your doctor can test for this
- rapid heartbeat (palpitation)
- asthma or asthma that is worse than usual
- confusion,hallucinations (possibly hearing or seeing things that are not there)
- paraesthesia (abnormal sensation such as pins and needles, tingling or numbness especially of hands and feet)
- drowsiness
- skin rash, redness and itchiness
- constipation or bloating
- loss of appetite
- weight gain or weight loss
- reactions to the sun. Your skin may become red, painful and swollen - do not sunbathe, use a sun bed, or expose your skin to artificial UV light
- nail changes
- hair loss
- head-spins (vertigo)
- sleepiness, inability to sleep, or abnormal dreams
- depression, nervousness
- changes to your eyesight
- feeling ill (malaise)
- ringing or buzzing in the ears (tinnitus)
- pancreatitis (inflammation of the pancreas)(very rare)

Medicines such as Tenoxicam may be associated with a small increased risk of heart attack or stroke. (see Section 2 - end of 'Take special care').

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store

- Keep out of the reach and sight of children.
- Do not use after the expiry date which is stated on the vial label and on the carton. The expiry date refers to the last day of that month.
- Store below 30ºC.
- Do not throw it away with your household waste or in water. Return all the unwanted medicine to your pharmacist. This will help to protect the environment.

6. Further information

What Tenoxicam injection contains

- The active ingredient is tenoxicam (20 mg).
- The other ingredients are: mannitol, ascorbic acid, disodium edetate, sodium hydroxide, tromethamine and hydrochloric acid (as a freeze-dried powder for dissolving in solvent).

What Tenoxicam injection looks like and contents of the pack

Tenoxicam is a green/yellow packed powder which is made into solution before it is given to you.

It is available in packs of 1 vial.

Marketing Authorisation Holder

Chemidex Pharma Ltd, trading as Essential Generics, 7 Egham Business Village, Crabtree Road, Egham, Surrey TW20 8RB.

Manufacturer

Laboratorios Alcalá Farma S.L., Carretera M-300, km 29,920, 28802-Alcalá de Henares (Madrid), Spain.

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