TENOXICAM Devatis Powder for Injection, 20 mg **DEVATIS**
Tenoxicam

Consumer Medicine Information (CMI)

What is in this leaflet

Please read this leaflet carefully before you start using TENOXICAM Devatis.

This leaflet answers some common questions about TENOXICAM Devatis. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given TENOXICAM Devatis against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, talk to your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What TENOXICAM Devatis is used for

TENOXICAM Devatis contains 20 mg tenoxicam as active substance, which is a medicine that belongs to a group called non-steroidal anti-inflammatory drugs (NSAIDs).

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

TENOXICAM Devatis relieves pain and reduces inflammation (swelling, redness and soreness) that may occur in:

- different types of arthritis, including rheumatoid arthritis, osteoarthritis and ankylosing spondylitis. As with other NSAID medicines, TENOXICAM Devatis will not cure your arthritic condition, but it may help to control pain, swelling and stiffness.
- muscle and bone injuries such as sprains, strains and tendonitis such as tennis elbow
- pain or swelling in or near a joint (bursitis)
- inflammation surrounding the shoulders (shoulder-hand syndrome) or hips
- degenerative joint disease (arthrosis)
- following surgery

Your doctor may have prescribed TENOXICAM Devatis for another reason.

Ask your doctor if you have any questions about why TENOXICAM Devatis has been prescribed for you.

This medicine is available only with a doctor's prescription. There is no evidence that it is addictive.

Before you use TENOXICAM Devatis

When you must not use it

You must not be given TENOXICAM Devatis if you have had an allergic reaction to:

- Tenoxicam or any ingredients listed at the end of this leaflet
- Aspirin (e.g. Aspro®, Disprin®, Cartia®)

- Any other NSAID medicine, which may include ibuprofen (Brufen®, Nurofen®, Panafen®), mefenamic acid (Ponstan®), diclofenac sodium (Voltaren®, Cataflam®, Apo-Diclo®, Diclax®, Flameril®), naproxen (Naprosyn®, Synflex®, Naprogesic®), indomethacin (Indocid®, Rheumacin®), celecoxib (Celebrex®), ketoprofen (Orudis®, Oruvail®), sulindac (Daclin®), tiaprofenic acid (Surgam®), meloxicam (Mobic®), etoricoxib (Arcoxia®)

Many medicines used to treat headache, period pain and other aches and pains contain aspirin or NSAID medicines. If you are not sure if you are taking any of these medicines, ask your pharmacist.

Symptoms of an allergic reaction to these medicines may include:
- asthma, wheezing or shortness of breath
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- hives, itching or skin rash
- fainting
- blocked or running nose

If you are allergic to aspirin or NSAID medicines and take TENOXICAM Devatis, these symptoms may be severe.

Do not take TENOXICAM Devatis if:
- **you have asthma**
- **you have a peptic ulcer (ulcer in the stomach or duodenum), or have had a peptic ulcer in the past**
- **you have, or have had, a stomach problem causing pain, nausea, vomiting, vomiting blood and/or blood in the bowel motions**
- **you have a tendency to spontaneously bleed or bleed when incurring minor accidents (hemorrhagic diathesis)**
- **you have severe liver or kidney disease**
- **you have severe heart failure**
- **You are in the third trimester of pregnancy**

You must not be given TENOXICAM Devatis if the packaging is torn or shows signs of tampering or after the expiry date printed on the pack.

If you are not sure whether you should be given TENOXICAM Devatis, talk to your doctor.

Safety and effectiveness of TENOXICAM Devatis have not been established for children and adolescents.

Before you start to use it

Tell your doctor if:

1. **You are pregnant or plan to become pregnant**
   TENOXICAM Devatis may make it difficult to get pregnant and is not recommended in women trying to get pregnant. TENOXICAM Devatis may affect you or your developing baby if you take it during pregnancy. TENOXICAM Devatis is not recommended for use in the first and second trimester of pregnancy unless the benefits of treatment outweigh the risk to the unborn baby. TENOXICAM Devatis must not be used in the third trimester of pregnancy
   Do not take TENOXICAM Devatis if you are in labor as it may harm you and/or affect the baby.
   Use of NSAIDs may increase the risk of miscarriage and congenital malformation particularly when taken in early pregnancy.
   As with other NSAIDs, use of this medicine during the third trimester of pregnancy is contraindicated due to the possibility of delaying birth and fetal complications.

2. **You are breast-feeding or intend to breast-feed**
   TENOXICAM Devatis is not recommended while you are breast-feeding. If there is a need to consider using TENOXICAM Devatis while you are breast-feeding your doctor will discuss the risks and benefits of using it.

3. **You have or have had any medical conditions, especially the following:**
   - liver disease
   - kidney disease
   - diabetes
   - a tendency to bleed
   - heart failure or heart disease or uncontrolled blood pressure
   - you have had a stroke
   - you smoke (increases the risk of heart disease)
   - you retain fluid
   - you have high cholesterol
   - history of inflammatory bowel disease (ulcerative colitis; Crohn's disease)

4. **You have recently had or are about to have major surgery**

5. **You currently have an infection**
   If you take TENOXICAM Devatis while you have an infection, it may hide some of the signs of an infection (e.g. pain, fever). This may make you think, mistakenly, that you are better or the infection is not serious.

If you have not told your doctor about any of the above, tell them before you start being given TENOXICAM Devatis.

Using other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are using TENOXICAM Devatis.

Some medicines may interfere with TENOXICAM Devatis. These include:
- diuretics, also called fluid or water tablets
- diabetic medicines taken by mouth, medicines used to treat diabetes
- probenecid, a medicine used to treat gout
- corticosteroids - betamethasone, dexamethasone, prednisone, triamcinolone, cortisone, methylprednisolone, prednisolone, hydrocortisone, fludrocortisone
- aspirin, salicylates or other NSAID medicines
- methotrexate (Methoblastin®), a medicine used to treat arthritis and some cancers
- lithium (Lithicarb®, Priadel®), a medicine used to treat some types of depression
- anticoagulant medicines - warfarin (Coumadin®, Marevan®), heparin (Clexane®, Fragmin®, Innohep®, Monoparin®, Multiparin®), dabigatran (Pradaxa®), apixaban (Eliquis®), rivaroxaban (Xarelto®). Medicines used to stop blood clots
- selective serotonin reuptake inhibitors (SSRI's) - a class of medicines used to treat some types of depression (eg: Aropax®, Cipramil®, Prozac®)
- antihypertensives, medicines used to treat high blood pressure
- Ciclosporin, used for transplant rejection episodes

These medicines may be affected by TENOXICAM Devatis, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.
Your doctor or pharmacist has more information on medicines to be careful with or avoid while using

TENOXICAM Devatis.

Ask your doctor or pharmacist if you are not sure about this list of medicines.

How to use TENOXICAM Devatis

Follow all directions given to you by your doctor or pharmacist carefully.
They may differ from the information contained in this leaflet.

How much to use
Your doctor will decide what dose and how long you will receive TENOXICAM Devatis. This depends on the condition being treated and your response to the treatment.

When to use it
For most conditions, it is usually given once daily at the same time of each day.

How long to use it
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.

How it is given
TENOXICAM is a sterile powder which is dissolved and diluted with suitable sterile fluids.
It is given by:
- direct injection into a vein,
- deep injection into a large muscle.

TENOXICAM must only be prepared and given by a doctor or nurse.

If you forget to take TENOXICAM Devatis
Necessary precautions will be taken since TENOXICAM will be administered to you by a doctor or nurse.
Do not take a double dose to make up for the dose that you missed.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

While you are using TENOXICAM Devatis

Things you must do
Tell all doctors, dentists and pharmacists who are treating you that you are using TENOXICAM Devatis.
Tell your doctor if you become pregnant while using TENOXICAM Devatis.

If you are going to have surgery tell your surgeon you are using TENOXICAM Devatis.

If you get an infection while using TENOXICAM Devatis, tell your doctor.
TENOXICAM may hide some of the signs of an infection and may make you think, mistakenly, that you are better or it is not serious. Signs of an infection may include fever, pain, swelling and redness.
Tell your doctor if you have any eye (vision) problems, or if they develop while using TENOXICAM Devatis.
Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.
Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Tell your doctor if you feel that TENOXICAM Devatis is not helping your condition.
Be sure to keep all of your appointments with your doctor so that your progress can be checked.
Your doctor may wish to perform tests from time to time to monitor your condition.

Things you must not do
Do not give TENOXICAM Devatis to anyone else, even if they have the same condition as you.

Do not take other medicines whether they require a prescription or not without first telling your doctor or consulting a pharmacist.

Things to be careful of
Be careful driving or operating machinery until you know how TENOXICAM Devatis affects you.
As with other NSAID medicines, TENOXICAM Devatis may cause dizziness, lightheadedness or vision problems in some people. Make sure you know how you react to TENOXICAM Devatis before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed, or your vision is altered. If this occurs do not drive. If you drink alcohol, dizziness or light-headedness may be worse.

In case of overdose

If you are given too much (overdose)
As TENOXICAM Devatis is given to you under the supervision of your doctor, it is very unlikely that you will receive too much.
The following are some symptoms which may or may not occur:
- pain or tenderness in the stomach
- stomach upset including nausea (feeling sick), vomiting, heartburn, indigestion or cramps
- difficulty breathing

However, if this is the case, immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much TENOXICAM Devatis. Do this even if there are no signs of discomfort or poisoning.

Side effects

Tell your doctor or nurse as soon as possible if you do not feel well while you are being treated with TENOXICAM Devatis.

This medicine helps most people, but it may have unwanted side effects in some people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects.

Ask your doctor, nurse or pharmacist to answer any questions you may have.

Tell your doctor or nurse if you notice any of the following side effects and they worry you:
- stomach upset including nausea (feeling sick), heartburn, indigestion
- dizziness, lightheadedness
- headache

Tell your doctor immediately or go to your nearest Accident and Emergency Centre if you notice any of the following:
- vomiting blood or material that looks like ground coffee

- bleeding from the back passage (rectum), black sticky bowel motions (stools) or bloody diarrhea
- sudden swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- severe pain or tenderness in any part of the stomach
- severe skin reactions with blistering and/or severe rash or areas of unusually dark and swollen skin
- asthma, wheezing, shortness of breath
- pain or tightness in the chest
- eye problems such as blurred vision
- fast or irregular heartbeats, also called palpitations
- swelling of the hands, ankles or feet

These are serious side effects. You may need urgent medical attention.

The most common side effects are dyspepsia, nausea, abdominal pain, dizziness or headaches.

Tell your doctor if you notice anything else that is making you feel unwell, even if you think the problems are not connected with this medicine and are not referred to in this leaflet.

Ask your doctor or pharmacist if you don't understand anything in these lists.

This is not a complete list of all possible side effects. Other adverse effects not listed above may also occur in some patients and there may be some side effects not yet known. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using TENOXICAM Devatis

Storage

TENOXICAM Devatis will be stored in the pharmacy or on the ward. Store at or below 30°C, protected from light.

Do not store TENOXICAM Devatis or any other medicine in a bathroom or near a sink.
Do not leave it in the car or on window sills. Heat and dampness can destroy some medicines.

Keep TENOXICAM Devatis where children cannot reach it.
A locked cupboard at least one-and-a-half meters above the ground is a good place to store medicines.

Disposal

Do not use TENOXICAM Devatis after the expiry date, which is stated on the packaging.
If your doctor advises you to stop using TENOXICAM Devatis or the medicine has passed its expiry date, ask your pharmacist how to throw away medicines you no longer use. Do not throw away any medicines via wastewater. These measures will help protect the environment.

Product description

What it looks like

TENOXICAM Devatis is a yellow-green colored lyophilized mass in a glass vial with a rubber stopper. The powder is dissolved and diluted with suitable sterile fluids before it is used.

Ingredient

Active ingredient(s):
Each vial contains 20 mg Tenoxicam.

Inactive ingredients:
Ascorbic Acid, Disodium edetate, Mannitol, Sodium hydroxide, Trometamol, Hydrochloric acid (for pH adjustment)

TENOXICAM Devatis does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

Sponsor

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www.devatis.nz

Date of Preparation

This leaflet was revised in September 2024.

THE FOLLOWING INFORMATION IS INTENDED FOR HEALTHCARE PROFESSIONALS ONLY

Posology/frequency and duration of administration
Undesirable effects may be minimized by using the lowest effective dose for the shortest possible duration necessary to control symptoms.
For all indications except post-operative pain, a daily single dose of 20 mg should be administered at the same time of day.
For post-operative pain the recommended dose is 40 mg daily for 5 days.
In treatment of chronic disorders the therapeutic effect of tenoxicam is evident early in treatment and there is a progressive increase in response over time. In chronic disorders, daily doses higher than 20 mg are not recommended since this would increase the frequency and intensity of unwanted reactions without significantly increasing efficacy.
For patients needing long-term treatment a reduction to a daily oral dose of 10 mg may be tried for maintenance (this cannot be achieved using this product, i.e. a tablet presentation should be used).

Method of administration
The lyophilized power in the vial should be dissolved in 2 ml of sterile water for injection. The prepared solution should be administered by intramuscular (IM) or intravenous (IV) bolus injection immediately.
Where indicated, treatment is initiated with single dose by IV or IM administration daily for one or two days and continued tenoxicam given by oral or rectal route.
Lyophilized powder for injection is developed for IM or IV bolus administration; due to possibility of precipitation it should not be used by infusion.

Additional information regarding special populations

Renal impairment
The above dosage recommendations also apply to patients with renal impairment. However, it is recommended that when tenoxicam is used in patients with renal impairment, kidney functions should be carefully monitored. Dosage should be minimised in patients with renal impairment. It should not be used in patients with severe renal impairment.

Hepatic impairment
The above dosage recommendations also apply to patients with hepatic impairment. However, it is recommended that when tenoxicam is used in patients with hepatic impairment, liver functions should be carefully monitored. Dosage should be minimised in patients with hepatic impairment. It should not be used in patients with severe hepatic impairment**.**

Pediatric population
No dosage recommendations have been established for children and adolescents due to insufficient data. Not to be used in this age group.

Geriatric population
The elderly have an increased risk of gastrointestinal bleeding, ulceration or perforation which may be fatal. These patients should commence treatment on the lowest dose available and combination therapy with protective agents (e.g. misoprostol or proton pump inhibitors) should be considered for these patients who are using concurrent and also for patients requiring concomitant low dose salicylates, or other drugs likely to increase gastrointestinal risk.

Please see the Data Sheet for detailed information regarding Contraindications, Special warnings and precautions for use, Interactions, and other clinical information. You can read and download the Data Sheet from the Medsafe website (www.medsafe.govt.nz).