

Tenoxicam 20 mg Tablets

(Tenoxicam)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- 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 signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Tenoxicam Tablets are and what they are used for
2. What you need to know before you take Tenoxicam Tablets
3. How to take Tenoxicam Tablets
4. Possible side effects
5. How to store Tenoxicam Tablets
6. Contents of the pack and other information

Ennogen Healthcare

1 What Tenoxicam Tablets are and what they are used for

The name of your medicine is Tenoxicam 20 mg Tablets.

Tenoxicam is a non-steroidal anti-inflammatory drug (NSAID), which relieves pain and inflammation associated with muscle and joint disorders and other painful conditions.

Tenoxicam 20 mg Tablets are used to relieve pain and reduce swelling in conditions that include: rheumatoid arthritis, osteoarthritis and other musculoskeletal disorders including sprains and strains, sciatica, bursitis and soft-tissue injuries.

2 What you need to know before you take Tenoxicam Tablets

Do NOT take Tenoxicam Tablets if you:

- are allergic (hypersensitive) to tenoxicam or any of the ingredients of this medicine (listed in section 6).
- are allergic to Aspirin, or any other NSAIDs (such as ibuprofen, salicylates or diclofenac).
- are in last 3 months of pregnancy.
- have a peptic ulcer (ulcer in your stomach or duodenum) or bleeding in your stomach, or have had two or more episodes of peptic ulcers, stomach bleeding or perforations.
- have had stomach or bowel problems after you have taken other NSAIDs.
- have severe problems with your heart, kidney or liver.

Do not take Tenoxicam Tablets if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Tenoxicam Tablets.

Warnings and precautions

Talk to your doctor before taking Tenoxicam Tablets if you:

- Have heart problems, you have had a stroke or think you may be at risk of these conditions (for example if you have high blood pressure, diabetes, high cholesterol or are a smoker)
- Asthma or allergies (like hayfever) or have had swelling of the face, lips, eyes or tongue in the past.
- Are elderly (you are more likely to suffer problems).
- Problems with your kidneys or liver.
- Problems with the way that your blood clots.
- Low blood volume (caused by bleeding or severe dehydration).
- Problems with the blood vessels (arteries) anywhere in your body.
- Too much fat (lipid) in your blood (hyperlipidaemia).
- An autoimmune condition, such as 'systemic lupus erythematosus' (SLE, causes joint pain, skin rashes and fever) and ulcerative colitis or Crohn's disease (conditions causing inflammation of the bowel, bowel pain, diarrhoea, vomiting and weight loss).
- Are going to have an operation, such as a replacement hip or other major surgery.
- Stop taking this medicine immediately if you develop the symptoms and signs of Stevens-Johnson syndrome (SJS), toxic epidermal necrosis (TEN) and exfoliative dermatitis, such as skin rash with blisters on your skin and the mucous membranes of your mouth, nose, eyes and genitals.

If any of the above apply to you, or if you are not sure, talk to your doctor or pharmacist before you take Tenoxicam Tablets.

Other medicines and Tenoxicam

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines. In particular, tell your doctor or pharmacist if you are taking:

- Other NSAIDs, like aspirin, ibuprofen or diclofenac.
- Medicines to stop your blood clotting, like warfarin, heparin or clopidogel.
- Sulfonamide medicines, like hydrochlorothiazide, acetazolamide, indapamide and including sulfonamide antibiotics (for infections).

- A sulfonylurea (for diabetes), like glimepiride or glipizide.
- An 'ACE inhibitor' or any other medicine for high blood pressure like cilazapril, enalapril or propranolol.
- A diuretic (water tablet) for high blood pressure, like furosemide.
- A 'cardiac glycoside' (for heart problems), like digitoxin.
- A steroid (for swelling and inflammation), like hydrocortisone, prednisolone and dexamethasone.
- A 'quinolone antibiotic' (for infections), like ciprofloxacin or moxifloxacin.
- Lithium (for mental health problems).
- Methotrexate (used to treat skin problems, arthritis or cancer).
- Ciclosporin or tacrolimus (for skin problems or after an organ transplant).
- Zidovudine (used to treat AIDS and HIV infections).
- Mifepristone (used to end pregnancy or to bring on labour if the baby has died).
- SSRI's (medicines used to treat depression such as fluoxetine, citalopram, paroxetine, fluvoxamine).
- Antacids (used to treat conditions such as indigestion, heartburn).
- Dextromethorphan (found in many cough medicines)
- Colestyramine (used to treat high cholesterol).
- Probenecid (used to treat gout).

If any of the above apply to you, or if you are not sure, talk to your doctor or pharmacist before you take Tenoxicam Tablets.

Pregnancy, breast-feeding and fertility

You should not take Tenoxicam Tablets during the last 3 months of pregnancy as it may affect the baby's circulation. Do not take Tenoxicam Tablets if you are in the last 3 months of pregnancy as it could harm your unborn child or cause problems at delivery. **It can cause kidney and heart problems in your unborn baby. It may affect your and your baby's tendency to bleed and cause labour to be late or longer than expected.** You should not take Tenoxicam Tablets during the first 6 months of pregnancy unless absolutely necessary and advised by your doctor. If you need treatment during this period or while you are trying to get pregnant, the lowest dose for the shortest time possible should be used. **If taken for more than a few days from 20 weeks of pregnancy onward, Tenoxicam Tablets can cause kidney problems in your unborn baby that may lead to low levels of amniotic fluid that surrounds the baby (oligohydramnios) or narrowing of a blood vessel (ductus arteriosus) in the heart of the baby. If you need treatment for longer than a few days, your doctor may recommend additional monitoring.**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Tenoxicam Tablets may make it more difficult to become pregnant. You should tell your doctor if you are planning to become pregnant or if you have problems becoming pregnant.

If you are breast-feeding, avoid taking this medicine because very small amounts of tenoxicam have been found in breast milk.

Driving or using machines

Sometimes these tablets can make you tired, feel dizzy or drowsy, have problems with your eyesight and balance, depressed or have difficulty sleeping. Talk to your doctor if any of these happen to you and do not drive or operate machinery if you experience these effects whilst using this medicine.

Other special warnings

Tenoxicam tablets contain lactose. You should not take these tablets without consulting your doctor first if you have an intolerance to lactose or some sugars.

3 How to take Tenoxicam Tablets

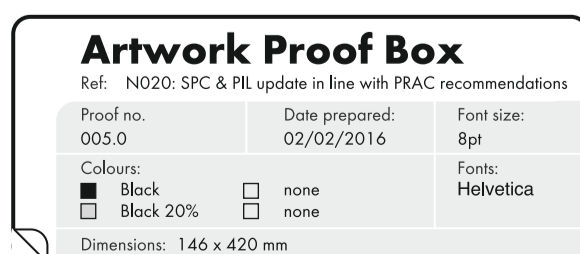
Always take Tenoxicam Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The tablets should not be crushed or chewed, but swallowed whole with plenty of water, preferably with or after food.

Adults and children over 12:

The usual dose is one tablet taken as a single dose at the same time every day.

Continued on the next page >>



Elderly:

Your doctor will decide your dose, it will usually be lower than that for other adults. While you are taking 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 aged under 12 years:

This medicine is not recommended for children under 12 years of age.

The elderly and people with liver and kidney problems:

Your doctor will decide your dose, it will usually be lower than that for other adults.

If you forget to take a dose:

If you forget to take your medicine do not take a double dose to make up for a missed dose. When you remember, take the next prescribed dose and continue with the treatment. If you are concerned, consult your doctor or pharmacist.

If you take more Tenoxicam Tablets than you should

If you take too many Tenoxicam Tablets than you should, contact your doctor or hospital accident and emergency department immediately. You may experience sickness, headache, drowsiness, dizziness and blurred vision. There have been isolated reports of more serious symptoms such as a seizure, renal failure, heart failure, liver failure, abnormal bleeding problems, abnormal kidney problems or coma. You should seek immediate medical advice or go to the nearest hospital straight away and take this medicine with you.

If you stop taking Tenoxicam Tablets

Do not stop taking your medicine without consulting your doctor as the original symptoms may return.

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

4 Possible side effects

Like all medicines Tenoxicam can cause side effects, although not everyone will get them. Medicines such as Tenoxicam may be associated with a small increased risk of heart attack ('myocardial infarction') or stroke.

Important side effects to look out for: Stop taking Tenoxicam and tell a doctor straight away if any of the following side effects happen. You may need urgent medical treatment:**Serious stomach or gut problems, signs include:**

- Bleeding from the stomach, seen as vomit which has blood in it, or bits that look like coffee grounds.
- Bleeding from your back passage (anus), seen as passing black sticky bowel motions (stools) or bloody diarrhoea.
- Ulcers or holes forming in your stomach or gut. Signs include upset stomach, stomach pain, fever, feeling or being sick.
- Problems with your pancreas. Signs include severe stomach pain which spreads to your back.
- Worsening of ulcerative colitis or Crohn's disease, seen as pain, diarrhoea, vomiting and weight loss.

Allergic reactions, signs include:

- Sudden swelling of your throat, face, hands or feet.
- Difficulty breathing, tightness in your chest.
- Skin rashes, blisters or itching.

Severe skin rashes, signs include:

- A severe rash that develops quickly, with blisters or peeling of your skin and possibly blisters in your mouth, throat or eyes. Fever, headache, cough and aching body may happen at the same time.

Liver problems, signs include:

- Yellowing of your skin or the whites of your eyes (jaundice).
- Feeling tired, loss of appetite, feeling or being sick and pale coloured stools (hepatitis) and problems (including hepatitis), shown in blood tests.

Heart attack, signs include:

- Chest pain which may spread to your neck and shoulders and down your left arm.

Stroke, signs include:

- Muscle weakness and numbness. This may only be on one side of your body.
- A suddenly altered sense of smell, taste, hearing or vision, confusion.

Meningitis, signs include:

- Fever, feeling or being sick, a stiff neck, headache, sensitivity to bright light and confusion (most likely in people with autoimmune conditions such as 'systemic lupus erythematosus').

If you notice any of the serious side effects mentioned above, stop taking Tenoxicam Tablets and tell your doctor straight away.

Other possible side effects:**Very common (affects more than 1 in 10 people):**

- inflammation of the mouth and/or lips, with or without ulceration

Common (affects 1 in 100 people):

- Inflammation of the stomach lining, seen as upset stomach, bloating, nausea, pain, hiccups
- Dizziness

- Headache
- Heartburn

Uncommon (affects 1 in 1,000 people):

- Itching
- Skin redness
- Skin rashes, hives, pimples and blisters on your hand, body or face
- Kidney problems
- Feeling tired
- Difficulty sleeping
- Swelling and fluid retention
- Constipation
- Diarrhoea
- Vomiting
- Mouth ulceration
- Dry mouth
- Decreased appetite
- Vertigo, seen as feeling that the room is moving or spinning
- A fluttering feeling in your heart (palpitations), slow heart beat or high blood pressure

Rare (affects 1 in 10,000 people):

- Weight loss
- Hyperglycemia seen as increased blood sugar
- Changes in your patterns of dreaming
- Depression
- Nervousness

Very rare (affects less than 1 in 10,000 people):

- Changes to your nails
- Hair loss (alopecia)
- Pancreatitis (inflammation of the pancreas)

Not known (frequency cannot be estimated from the available data):

- Blood problems, like anaemia or changes to the numbers of white blood cells
- Changes to your eyesight, swollen or irritated eyes
- 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
- Tinnitus (ringing in the ears)
- Problems with the way your heart pumps blood around the body. Signs may include tiredness, shortness of breath, feeling faint, general pain
- Hypertension (high blood pressure)
- Vasculitis, seen as fever, loss of appetite, weight loss, tiredness, general aches and pains
- Skin being more sensitive to the sun
- Female infertility*

*Isolated cases of impaired female fertility (reversible on stopping)

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 MHRA Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Tenoxicam Tablets

Keep all medicines out of the sight and reach of children. Your medicines can harm them.

Do not use Tenoxicam Tablets after the expiry date which is stated on the carton. The expiry date refers to the last day of that month. Do not store above 25°C.

Do not use Tenoxicam Tablets if you notice any chipped tablets or any other visible signs of deterioration.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6 Contents of the pack and other information

What Tenoxicam Tablets contains

Each tablet contains 20 mg of the active ingredient tenoxicam. The other ingredients are lactose, maize starch, pregelatinised starch, magnesium stearate, talc, colloidal silicon dioxide, hypromellose, titanium dioxide (E171) and iron oxide yellow (E172).

What Tenoxicam Tablets looks like and the contents of the pack

Tenoxicam Tablets are round, yellowish film-coated tablets.

They are available as blister packs, in carton boxes of 28.

Marketing Authorisation Holder and Manufacturer

The product licence holder is:
Ennogen Healthcare Ltd
Unit G4 Riverside Industrial Estate
Riverside Way
Dartford, DA1 5BS, UK

The manufacturer is:
Edmond Pharma,
Via dei Giovi, Paderno Dugnano, Milan, Italy.

This leaflet was last revised in April 2025.

ENV03

draft: 44004083
laetus code: supplier to add
mat.no.: supplier to add

Artwork Proof Box		
Ref: N020: SPC & PIL update in line with PRAC recommendations		
Proof no. 005.0	Date prepared: 02/02/2016	Font size: 8pt
Colours: <input checked="" type="checkbox"/> Black <input type="checkbox"/> Black 20%	<input type="checkbox"/> none <input type="checkbox"/> none	Fonts: Helvetica
Dimensions: 146 x 420 mm		