

## Tenoxicam 20 mg Tablets

(Tenoxicam)

**Please read this leaflet carefully before you start to take your medicine. It contains important information.**

- Keep this leaflet in a safe place because you may want to read it again.
- If you have any further questions, or if there is something you don't understand, please ask your doctor or pharmacist.
- This medicine has been prescribed for you. Never give it to someone else. It may not be the right medicine for them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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### 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.

- These potentially life-threatening skin rashes are often accompanied by flu-like symptoms. The rash may progress to widespread blistering or peeling of the skin
- The highest risk for occurrence of serious skin reactions is within the first weeks of treatment
- If you have developed Stevens-Johnson syndrome or toxic epidermal necrolysis with the use of tenoxicam, you must not be re-started on tenoxicam at any time
- If you develop a rash or these skin symptoms, seek immediate advice from a doctor and tell that you are taking this medicine.

**If you can say 'yes' to any of the above, ask your doctor or pharmacist for advice before taking this medicine. It may not be suitable for you or you may need to take special care when taking it.**

### 2 Before you take Tenoxicam Tablets

**DO NOT take Tenoxicam Tablets. Talk to your doctor if you:**

- are allergic (hypersensitive) to tenoxicam or any of the ingredients in this medicine (see section 6 Further information).
- have ever had an allergic reaction to ibuprofen, aspirin or other NSAIDs.
- are more than six months pregnant.
- 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 heart, kidney or liver failure.

**Talk to your doctor before taking Tenoxicam Tablets if you:**

- have any stomach or bowel disorders including ulcerative colitis or Crohn's disease
- suffer from or have a history of asthma
- are elderly (you are more likely to suffer problems)
- have Lupus (SLE) or any similar condition
- have kidney, liver or heart problems. Your doctor will probably recommend regular check-ups to monitor the function of your kidney, liver or heart
- have heart problems, previous stroke or think that you might be at risk of these conditions (for example if you have high blood pressure, diabetes or high cholesterol or are a smoker) you should discuss your treatment with your doctor or pharmacist.
- Medicines such as Tenoxicam may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke. Any risk is more likely with high doses and prolonged treatment.
- Do not exceed the recommended dose or duration of treatment
- are going to have an operation as these tablets can affect the clotting of your blood
- 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)
- You are going to have an operation, such as a replacement hip or other major surgery
- Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported with the use of tenoxicam, appearing initially as reddish target-like spots or circular patches often with central blisters on the trunk
- Additional signs to look for include ulcers in the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes)

**Taking other medicines**

Always tell your doctor or pharmacist about all the medicines you are taking. This means medicines you have bought yourself, including herbal remedies, as well as medicines on prescription from your doctor.

There may be problems if you take Tenoxicam Tablets with certain other medicines.

It is very important that you tell your doctor if you are taking the following:

- Antihypertensives like cilazapril, enalapril or propranolol (used to reduce your blood pressure)
- Diuretics like furosemide (used to treat high blood pressure)
- Cardiac glycosides (for example digoxin), used to treat heart problems
- Anticoagulants like warfarin, heparin or clopidogrel (used to prevent blood clotting)
- Lithium (used to treat depression)
- Methotrexate (used to treat certain cancers, rheumatoid arthritis and psoriasis)
- Ciclosporin and Tacrolimus (used after transplant operations)
- Mifepristone (used to terminate pregnancies or to bring on labour if the baby has died)
- Corticosteroids (used to treat inflammatory conditions), like hydrocortisone, prednisolone and dexamethasone
- Quinolone antibiotics (for infections), like ciprofloxacin or moxifloxacin
- Any other NSAID or COX-2 inhibitor e.g. aspirin, ibuprofen or celecoxib
- Medicines known as SSRIs (such as fluoxetine, citalopram, paroxetine, fluvoxamine), and an SNRI, venlafaxine, used to treat depression
- Zidovudine (used to treat HIV AIDS)
- Sulfonamide medicines, like hydrochlorothiazide, acetazolamide, indapamide and including sulfonamide antibiotics (for infections)
- A sulfonylurea (for diabetes), like gliclazide or glipizide
- Antacids (used to treat conditions such as indigestion, heartburn).

**Pregnancy and lactation**

You should not take Tenoxicam Tablets during the last 3 months of pregnancy as it may affect the baby's circulation. If you are in the first 6 months of pregnancy talk to your doctor before taking the medicine as Tenoxicam Tablets should only be taken if the benefit is likely to outweigh the risks.

Taking Tenoxicam Tablets may make it more difficult for you to get pregnant. You should talk to your doctor if you are planning to become pregnant or if you have problems getting pregnant.

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

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### 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.

### 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 too many tablets

If you take too many Tenoxicam Tablets than you should, contact your doctor or hospital accident and emergency department immediately. Signs of an overdose include headache, feeling sick, being sick, bleeding in the stomach, drowsiness, ringing in the ears and loss of consciousness.

### 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

Tenoxicam Tablets are suitable for most people, but like all medicines, they can sometimes cause side effects.

### Some side effects can be serious Stop taking Tenoxicam Tablets immediately and contact your nearest accident and emergency department if you notice:

- Allergic (hypersensitive) reaction. Symptoms include skin rash, itching, painful red areas, peeling or blistering, wheezing or shortness of breath, tightness in your chest, swollen face, lips, hands or fingers or a runny nose
- Pass blood in your faeces (stools/motions)
- Pass black tarry stools
- Vomit any blood or dark particles that look like coffee ground
- Worsening of colitis and Crohn's disease, seen as pain, diarrhoea, vomiting and weight loss
- You bruise more easily than usual or have frequent sore throats or infections
- You experience visual disturbances
- Yellowing of your skin or the whites of your eyes
- An unexpected change in the amount of urine produced and/or its appearance.

### Stop taking Tenoxicam Tablets and tell your doctor if you experience:

- Indigestion or heartburn
- Abdominal pain (pains in your stomach) or other abnormal stomach symptoms.

### Other side effects

#### Common side effects are:

- nausea (feeling sick)

- vomiting (being sick)
- flatulence (wind)
- constipation
- pancreatitis (severe upper stomach pain, often with nausea and vomiting)
- diarrhoea
- ulcers in the mouth
- swelling due to excess fluid in the body tissue
- abnormal flushing or blistering
- stomach ulcers.

#### Rare side effects are:

- headaches
- palpitations
- breathing troubles
- feeling tired and sleepy
- fever
- stiff neck
- pins and needles in your hands and feet
- depression, nervousness, confusion
- hallucinations (seeing things)
- sleep problems (insomnia, nightmares)
- ringing in the ears
- vertigo
- dizziness
- swollen eyes, blurred vision, eye irritation
- changes in body weight
- loss of appetite
- problems for women in getting pregnant
- nosebleeds
- increased glucose in the blood
- kidney or liver problems
- a rash caused by exposure to sunlight
- changes in the blood (results of blood tests) such as reduced platelet count, low number of white blood cells and reduced red blood cells (anemia).

#### Very rare side effects are:

- Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported (see section 2).
- Pancreatitis (inflammation of the pancreas)

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

- Changes to your eyesight
- 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

Medicines such as Tenoxicam may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke.

**If any of the side effects become serious or if you notice any side effects not mentioned in this leaflet, please tell your doctor or pharmacist.**

## 5 How to store Tenoxicam Tablets

Keep all medicines out of the reach and sight 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 Further 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:  
Sandoz Ltd,  
Frimley Business Park, Frimley,  
Camberley, Surrey, GU16 7SR, UK.

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

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