

Reutenox®

Tenoxicam

Film-coated tablets 20 mg

What is in this leaflet

Please read this leaflet carefully before you start taking Reutenox.

This leaflet answers some common questions about Reutenox. It does not contain all the available information. The most up-to-date Consumer Medicine Information can be downloaded from www.medsafe.govt.nz.

Reading this leaflet 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 taking Reutenox against the benefits this medicine is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may want to read it again.

What Reutenox is used for

Reutenox contains the active ingredient tenoxicam. It belongs to a group of medicines called Non-Steroidal Anti-Inflammatory Drugs (NSAIDS). These medicines work by relieving pain and inflammation (swelling, redness and soreness).

Reutenox is used to reduce inflammation that may occur in:

- different types of arthritis, including rheumatoid arthritis, osteoarthritis and ankylosing spondylitis. As with other NSAID medicines, Reutenox 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)
- menstrual cramps (period pain)
- following surgery
- gout (a disease with painful, swollen joints).

Your doctor may have prescribed this medicine for another reason.

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



Reutenox is available only with a doctor's prescription.

Reutenox is not addictive.

Before you take Reutenox

Reutenox is not suitable for everyone.

When you must not take it

Do not take Reutenox if you have:

- asthma
- a peptic ulcer (ulcer in the stomach or duodenum), or have had a peptic ulcer in the past
- or have had, a stomach problem causing pain, nausea, vomiting, vomiting blood and/or blood in the bowel motions
- a tendency to spontaneously bleed or bleed when incurring minor accidents (haemorrhagic diathesis)
- liver disease
- kidney disease
- severe heart failure.

Do not take Reutenox if you are in the third trimester of pregnancy.

Do not take Reutenox if you are allergic to any medicine containing tenoxicam, aspirin, other NSAIDs medicines or any of the ingredients listed at the end of this leaflet.

Many medicines used to treat headache, period pain and other aches and pains contain aspirin or NSAID medicine. These may include ibuprofen, mefenamic acid, diclofenac sodium, naproxen, indomethacin, celecoxib, ketoprofen, sulindac, tiaprofenic acid, meloxicam, etoricoxib.

If you are not sure if you are taking any of these medicines, ask your pharmacist.

Do not take it after the expiry date printed on carton and blister.

If you take it after the expiry date has passed, it may not work as well.

Do not take it if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start taking Reutenox, talk to your doctor or pharmacist.

Before you start to take it

Tell your doctor or pharmacist if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if 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
- history of inflammatory bowel disease (ulcerative colitis; Crohn's disease)
- history of stomach ulcers
- stroke
- high cholesterol
- fluid retention.

Tell your doctor if

1. you are pregnant or plan to become pregnant

Reutenox may make it difficult to get pregnant and is not recommended in women trying to get pregnant. Reutenox may affect you or your developing baby if you take it during pregnancy. Reutenox is not recommended for use in pregnant women unless the benefits of treatment outweigh the risk to the unborn baby.

Do not take Reutenox during the third trimester of your pregnancy as it may harm you and/or affect the baby.

- 2. you are breast-feeding or intend to breast-feed Reutenox is not recommended while you are breast-feeding. If there is a need to consider taking Reutenox while you are breast-feeding your doctor will discuss the risks and benefits of using it.
- 3. you smoke (increases the risk of heart disease)
- 4. you have recently had or are about to have major surgery
- 5. you currently have an infection If you take Reutenox 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.

Use with caution if you are over 65 years old.

Elderly persons are more sensitive to the effects of the medicine.

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

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking Reutenox.

Taking other medicines

Tell your doctor or pharmacist if you taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Tell any healthcare professional who is prescribing a new medicine for you that you are taking Reutenox.



Some medicines and Reutenox may interfere with each other. 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, a medicine used to treat arthritis and some cancers
- lithium, a medicine used to treat some types of depression
- anticoagulant medicines warfarin or heparin, medicines used to stop blood clots
- selective serotonin reuptake inhibitors (SSRI's) a class of medicines used to treat some types of depression
- antihypertensives, medicines used to treat high blood pressure
- cholestyramine, a medicine used to reduce high cholesterol levels in the blood
- dextromethorphan, a medicine used to treat dry coughs
- ciclosporin, a medicine used for transplant rejection episodes.

The above medicines may be affected by Reutenox, or may affect how well it works. You may need different amounts of your medicine, or take it at different times, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take Reutenox

Read the label carefully and follow all directions given to you by your doctor and pharmacist.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you how many Reutenox tablets to take each day depending on your condition. The usual dose is one 20 mg Reutenox tablet once a day however elderly patients or patients with kidney disease may need a lower dose.

For some conditions the dose may be different:

Period pain: the usual dose is one or two 20 mg Reutenox tablets once a day.

Pain following surgery: the usual dose is two 20 mg Reutenox tablets once a day for up to five days.

Attacks of gout: the usual dose is two 20 mg Reutenox tablets once a day for two days, then one 20 mg Reutenox tablet once a day for a further five days.

If you require long-term treatment, the daily dose may be reduced to half a 20 mg Reutenox tablet (10 mg) once a day.



Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take. This depends on your condition and whether or not you are taking any other medicines.

If you take the wrong dose, Reutenox may not work as well and your problem may not improve.

Swallow Reutenox whole with a full glass of water. Do not chew the tablet.

When to take it

Reutenox should be taken once daily, at about the same time each day.

Take Reutenox tablets during or immediately after a meal.

If you take Reutenox tablets on an empty stomach, they may cause stomach upset.

How long to take it

Your doctor will advise you on how long you need to take Reutenox tablets for.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take the next dose when you are meant to.

Do not try to make up for missed doses by taking more than one dose at a time. This may increase the chance of getting an unwanted side effect.

If there is still a long time to go before your next dose, take it as soon as you remember, and then go back to taking it as you would normally.

If you are not sure what to do, ask your doctor or pharmacist.

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

While you are taking Reutenox

Things you must do

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Reutenox. Likewise, tell any other doctors, dentists and pharmacists who are treating you that you are taking this medicine.

If you are going to have surgery, tell the surgeon and anaesthetist that you are taking this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.



If you get an infection while taking Reutenox, tell your doctor.

Reutenox 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 taking Reutenox.

If you need to have a blood test, tell your doctor that you are taking Reutenox. It may affect the results of some laboratory tests.

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.

Keep all of your doctor's appointments so that your progress can be checked. Your doctor may wish to perform tests from time to time to monitor your condition.

See your doctor if you feel that your condition is not improving or getting worse.

Things you must not do

Do not give your medicine to anyone else, even if they have the same condition as you.

This medicine is only intended for the person it has been prescribed for.

Do not take Reutenox to treat any other complaints unless your doctor tells you to.

Do not stop taking Reutenox or change the dosage without checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how Reutenox affects you. As with other NSAID medicines, Reutenox may cause dizziness, light-headedness or vision problems in some people. Make sure you know how you react to it 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, the effects may be worse.

Things that may help your condition (arthritis)

Some self help measures suggested below may help your condition.

Talk to your doctor, physiotherapist, or pharmacist about these measures and for more information.

 Weight - your doctor may suggest losing some weight to reduce the stress on your joints.



- Exercise may be recommended by your doctor or physiotherapist to help keep or improve movement and strengthen muscles. Ask a physiotherapist for an exercise plan suited to your condition. As a general rule if any exercise hurts then do not do it.
- **Rest** is important and is usually balanced with exercises and activity. Rest is needed when joints are hot, swollen or painful.
- Heat hot showers or baths may help to ease the pain and relax the muscles that can become tense with arthritis. Your physiotherapist or doctor can prescribe other forms of heat treatment.
- Physical aids are available to help with daily household tasks. For example, there
 are gadgets and aids to help turn on taps, remove screw tops, pick up objects and
 handles can be fitted in bathrooms. Ask your doctor to give you information.

In case of overdose

If you take too much

Immediately telephone your doctor, or the Poisons Information 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 Reutenox.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include:

- nausea (feeling sick), vomiting
- headache, drowsiness, blurred vision and dizziness
- difficulty breathing
- seizures, loss of consciousness.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Reutenox.

Like all medicines, Reutenox may occasionally cause side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

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

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- stomach upset including nausea (feeling sick), vomiting, indigestion, accumulation of gas
- constipation, diarrhoea
- dry mouth, mouth ulcers
- loss of appetite
- dizziness, light-headedness
- headache
- increased sensitivity to sun.

These side effects are usually mild.

Tell your doctor immediately if you notice any of the following:

- itching, rash or hives
- fatigue
- trouble sleeping
- eye problems such as blurred vision
- drowsiness
- confusional state
- hallucinations
- tingling or pricking sensation
- worsening of inflammatory bowel disease (ulcerative colitis; Crohn's disease).

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

Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- serious allergic reaction (sudden swelling of the face, lips, tongue, mouth or throat which may cause difficulty in swallowing or breathing)
- vomiting blood or material that looks like ground coffee
- bleeding from the back passage (rectum), black sticky bowel motions (stools) or bloody diarrhoea
- 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
- fast or irregular heartbeats, also called palpitations
- swelling of the hands, ankles or feet.

These are very serious side effects; you may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some patients.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After taking Reutenox

Storage

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they may not keep well.

Keep Reutenox in a cool dry place where the temperature stays below 30°C.

Do not store it or any other medicine in the bathroom, near a sink, or on a window sill. Do not leave it in the car.



Heat and damp can destroy some medicines.

Keep it and any other medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Do not keep Reutenox past its expiry date.

Disposal

Return any unused medicine and any medicine past its expiry date (as shown on the labelling) to your pharmacy.

Product description

What it looks like

Reutenox is available in blister packs of 20 tablets. The tablets are yellow, biconvex, oval, film-coated tablets, scored on both sides. The tablets can be divided into equal doses.

Ingredients

Active ingredient:

tenoxicam

Inactive ingredients:

- lactose
- maize starch
- purified talc
- magnesium stearate
- hydroxypropyl methylcellulose
- polyethylene glycol 6000
- titanium dioxide
- iron oxide yellow.

Reutenox contains lactose.

It does **not** contain sucrose, tartrazine or any other azo dyes.

Sponsor details

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