Package leaflet: information for the user

Reutenox 20 mg coated 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 only. 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 notlisted in this leaflet.

What is in this leaflet:

1. What Reutenox is and what it is used for

Tenoxicam is a non-steroidal anti-inflammatory drug (NSAID) that acts by reducing inflammation.

Reutenox is indicated for:
- Treatment of painful inflammatory conditions of the muscles, joints, tendons and ligaments.
- Treatment of menstrual pain.

Reutenox has a strong and lasting effect upon pain and inflammation or swelling. It does not eliminate the causes of muscle and joint problems but improves the symptoms.

2. What you need to know before you take Reutenox

It is important that you use the lowest dose that relieves/controls the pain, and you must not take this medicine (Reutenox) longer than required to control your symptoms.

Do not take Reutenox:
- If you are allergic to tenoxicam or any of the other ingredients of this medicine (listed in section 6), or to any antirheumatic drugs or tranquillisers.
- If you develop asthma, rhinitis or skin disorders on taking medicines containing salicylates as active drug substance, or other non-steroidal anti-inflammatory drugs.
- If you have severe liver or kidney failure.
- If you have suffered a stomach or duodenal ulcer or bleeding or have experienced perforation of the digestive tube.
- If you have a severe heart failure.
- If you are in the last three months of pregnancy.

Warnings and precautions:
- If you have suffered or develop an ulcer, bleeding, or perforation of the stomach or duodenum that can manifest as severe or persistent abdominal pain and/or black stools, or even without previous warning symptoms. This risk is higher when high doses and long-term treatments are used in patients with a history of peptic ulcer, and in the elderly. In these cases, your doctor will consider using a stomach protecting medicine.
- **Ask your doctor**
- If you have liver or kidney disorders.
- If you have blood problems.
- If you suffer from heart disease or other illnesses.
- If you have allergies.
- If you are scheduled for surgery and are taking Reutenox, since the doctor will decide what to do with the treatment.
- If you simultaneously take medicines that affect blood clotting, such as corticosteroids, oral anticoagulants or ant platelet drugs like acetylsalicylic acid (aspirin). You also must ask your doctor if you use other medicines that could increase the risk of bleeding, such as corticosteroids and selective serotonin reuptake inhibitor antidepressant drugs.
- If you suffer Crohn's disease or ulcerative colitis, since medicines like Reutenox can worsen these conditions.

Cardiovascular precautions

Medicines such as Reutenox can be associated with a moderate increase in the risk of suffering a heart attack (myocardial infarction) or stroke. This risk is more likely to occur when high doses and long-term treatments are used. Do not exceed the recommended dose or duration of the treatment.

If you have heart problems, a history of stroke, or think you might be at risk of suffering these conditions (for instance, if you have high blood pressure, diabetes, increased cholesterol, or smoke), ask your doctor or pharmacist about this treatment.

Likewise, this type of medicine can cause fluid retention, particularly in patients with heart failure and/or high blood pressure (hypertension).

Skin rash that may prove life-threatening (Stevens-Johnson syndrome and toxic epidermal necrolysis) has been reported when using Reutenox. These rashes initially appear as red spots or circular blotches, often with a blister in their centre.

Other signs that may appear include sores in the mouth, throat, nose and genitals, and conjunctivitis (red and swollen eyes).

Such potentially life-threatening skin rashes are often associated with flu-like symptoms.

The rash may progress to form widespread blisters or scaling of the skin.

The risk of severe skin reactions is highest during the first weeks of treatment.

If you have developed Stevens-Johnson syndrome or toxic epidermal necrolysis when using Reutenox, you should not use this medicine again at any time.

If you develop a rash or any of these skin symptoms, you should visit a doctor immediately and tell him or her that you are taking this medicine.

Other medicines and Reutenox

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicine. This is very important, since when you take more than one drug at the same time, the effect may be enhanced or weakened. As an example, other medicines used to treat muscle or joint pain (salicylates or other non-steroidal anti-inflammatory drugs) can increase the frequency of gastrointestinal side effects (stomach disorders).

Caution is required when taking Reutenox with other medicines containing methotrexate as drug substance, since serious adverse effects may result, such as blood problems, liver or kidney disorders, or diarrhoea or inflammation and ulceration of the mouth.

The combination of Reutenox with lithium can cause undesirable effects such as trembling, vomiting, reddening of the skin and fluid retention. However, no clinically significant interactions have been observed between Reutenox and low molecular weight heparin.

Ask your doctor if you are taking medicines that contain the following active drug substances: salicylates, other non-steroidal anti-inflammatory drugs, potassium-sparing diuretics (agents that increase urine flow), alpha-adrenergic blockers, hydrochlorothiazide and angiotensin-converting enzyme inhibitors (AECIs) (agents that lower blood pressure), anticoagulants (agents that fluidify blood), anti-diabetic drugs (agents used to lower blood sugar levels) or corticosteroids (agents used to treat allergic reactions such as asthma or skin disorders, for example).

Ask your doctor if you need further information on this subject.

Pregnancy, breast feeding and fertility

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

Pregnancy

Since the use of medicines like Reutenox has been associated with an increased risk of suffering congenital anomalies/ miscarriages, its administration is not recommended during the first and second trimester of pregnancy, unless considered strictly necessary. In these cases, both the dose and duration of treatment should be as limited as possible.

The administration of Reutenox is contraindicated in the last three months of pregnancy.

Breast feeding

Reutenox is excreted in small amounts in breast milk. Your doctor will decide whether you can take Reutenox during the breast feeding period.

Fertility

In the case of women of child-bearing potential, it must be taken into account that medicines like Reutenox have been associated with decreased fertility.

Driving and using machines

The ability to drive and use machines may be affected by Reutenox, depending on individual response to the drug. Patients treated with Reutenox therefore should check their reflexes before driving or using machines.

Reutenox contains lactose

This medicine contains lactose. If your doctor has indicated that you suffer intolerance to certain sugars, ask him or her before taking this medicine.

3. How to take Reutenox

Carefully follow the Reutenox administration instructions given to you by your doctor. Check with your doctor or pharmacist if you are not sure.

Reutenox should be taken always at the same time of day, preferably during or immediately after meals. Swallow the tablets whole (without chewing), with the help of water or some non-alcoholic beverage. The tablets are scored to facilitate dividing into two halves.
One tablet (20 mg) a day is enough for the treatment of rheumatic diseases or muscle and joint pain. Nevertheless, the doctor may decide to prescribe a different dose.
Depending on the severity of the pain, one or two tablets a day are recommended for the treatment of menstrual pain.
In any case, do not exceed a maximum single daily dose of two tablets, corresponding to 40 mg of tenoxicam.
Reutenox affords relief shortly after the start of treatment, and this relief may increase over time. In prolonged treatments, the doctor may decide to prescribe lower daily doses to maintain the treatment effect.

Use in the elderly:
No specific dose modification is normally required in elderly patients. In patients with liver, kidney, heart, blood or stomach problems, the doctor will decide whether is advisable to administer Reutenox at lower doses, or whether the patient should not take it. Always take this medicine exactly as described in this leaflet or as your doctor has told you.
Do not modify the dose prescribed by your doctor. Tell your doctor if you think the effect of this medicine is either too strong or too weak.
Do not discontinue the treatment on your own accord, since the doctor is the person who should decide the duration of treatment.
If your doctor considers it appropriate, treatment with Reutenox can be resumed later on.
Reutenox is prescribed by the doctor on an individual basis for each patient, and in no case should it be passed on to other people.
Treatment with Reutenox can be supplemented by other measures, such as hot or cold baths, exercise or massages. These supplementary treatments are indicated by the doctor on an individualised basis for each patient.
Ask your doctor or pharmacist if you require more information on Reutenox.
If you take more Reutenox than you should
If you or some other person has taken too much Reutenox, report to the doctor, pharmacist or nearest hospital immediately, or call the Toxicological Information Service. Phone: 00 34.91.562.04.20, specifying the medicine and amount taken.

If you forget to take Reutenox
Do not take a double dose to make up for a forgotten dose.
If you forget to take a dose, take it as soon as you remember, and then continue the treatment as usual.

4. Possible side effects
Like all medicines, Reutenox can cause side effects, although not everybody gets them.
Reutenox is well tolerated by most patients.
The most common side effects are loss of appetite and dry mouth. In some cases patients may experience fatigue, sleep disturbances, itching, reddening of the skin and headache. These effects are generally transient and do not require treatment discontinuation.

Gastrointestinal:
The most common adverse events of medicines like Reutenox are of a gastrointestinal nature: peptic ulcer, gastric bleeding, perforation (in some cases fatal), particularly in the elderly. Nausea, vomiting, diarrhoea, flatulence, constipation, heartburn, abdominal pain, blood in stools, mouth sores, worsening of ulcerative colitis and Crohn's disease have also been observed. Gastritis has been less frequently reported.

Cardiovascular:
Medicines like Reutenox, in particular, can be associated with a moderate increase in the risk of heart attack (myocardial infarction) or stroke.

Skin:
In very rare cases, life-threatening skin rash conditions (Stevens-Johnson syndrome, toxic epidermal necrolysis) may develop (see section 2).

Liver:
Medicines like Reutenox can be associated with liver disorders causing a yellowish colouring of the skin and eyes, sometimes with high fever or swelling and tenderness in the upper abdomen.
If any of the following reactions occur: ellowish colouring of the skin or eyes, discontinue the treatment and inform your doctor IMMEDIATELY.
In exceptional cases, patients may develop swelling of the ankles, reddening of the skin, increased sensitivity to sunlight, blue marks, visual disturbances, vomiting with blood, severe stomach ache, swelling of the face, asthma or flu-like symptoms, vasculitis and hepatitis. Ask the doctor immediately if you experience any of these symptoms. He or she will decide whether treatment with Reutenox should be discontinued.
If you feel any side effect that you suffer is serious, or if you notice any side effect not mentioned in this leaflet, inform your doctor or pharmacist.

5. How to store Reutenox
Keep this medicine out of the sight and reach of children.

Store in the original container.

Do not use this medicine after the expiry date which is stated on the container after "EXP". The expiry date is the last day of the indicated month.

Do not throw away any medicines via wastewater or household waste. Place the containers and medicines you no longer need in the SIGRE point at the pharmacy. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information
What Reutenox contains
- The active substance is tenoxicam.
- The other ingredients are lactose, maize starch, talc, magnesium stearate, macrogol 6000, hypromellose, titanium dioxide (E-171) and iron oxide (E-172).

What Reutenox looks like and contents of the pack
Reutenox 20 mg is supplied in the form of scored, coated tablets for oral administration, in packages containing 20 and 500 tablets.
Not all package sizes may be available.

How supplied:
Reutenox 20 mg granules for oral suspension: granules for oral suspension in single-dose sachets containing 5 g of granules. Package containing 20 sachets.

Marketing authorisation holder and manufacturer

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Detailed information on this medicine is available on the Spanish Medicines Agency (AEMPS) web site: http://www.aemps.gob.es/

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