

PATIENT INFORMATION LEAFLET

TROCMETAM 20 mg lyophilized powder for injection

Intramuscular or intravenous administration.

Sterile

- **Active Substance:** Each vial contains 20 mg Tenoxicam.
- **Excipients:** Mannitol, sodium hydroxide, trometamol, sodium metabisulfite, disodium edta, water for injection, sodium hydroxide and/or hydrochloric acid for pH adjustment

Before using this medicine, read all of this PATIENT INFORMATION LEAFLET carefully. Because, this leaflet includes important information for you.

- *Keep this PATIENT INFORMATION 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.*
- *During the use of this medicine, tell that you are using this medicine when you go to a doctor or hospital.*
- *Follow these instructions exactly as written. Do not use **higher or lower** dose other than your recommended dose.*

In this leaflet:

1. *What TROCMETAM is and what it is used for?*
2. *What you need to know before you take TROCMETAM*
3. *How to take TROCMETAM?*
4. *Possible side effects*
5. *How to store TROCMETAM?*

headlines are included.

1. What TROCMETAM is and what it is used for?

TROCMETAM contains 20 mg of tenoxicam per vial.

Tenoxicam, the active ingredient of TROCMETAM, belongs to a group of drugs called non-steroidal anti-inflammatory drugs (NSAIDs) with anti-inflammatory and antirheumatic activity.

TROCMETAM is effective in the symptomatic treatment of calcification (osteoarthritis), rheumatoid arthritis disease that causes pain and deformity in the joints and ankylosing spondylitis, a painful progressive rheumatic disease with stiffness in the back joints and in the treatment of gout (acute gout arthritis), acute musculoskeletal pain, postoperative pain and painful menstruation.

2. What you need to know before you take TROCMETAM

DO NOT TAKE TROCMETAM under the following circumstances

If:

- you are allergic to tenoxicam or any of the other ingredients of TROCMETAM (see list of excipients),
- If you have allergic reactions to salicylate or other NSAID medications such as asthma, cold or hives,
- You have previously experienced bleeding or perforation in your stomach while taking NSAID,
- You have ever had any problems with your stomach or gut like an ulcer or bleeding,
- You have severe problems with your kidneys, liver or heart,
- In the treatment of pain before or after cardiovascular bypass surgery
- you are in the last trimester of pregnancy,

USE TROCMETAM WITH CARE in the following cases

If,

- You have heart problems (uncontrolled hypertension, congestive heart failure, respiratory distress due to heart failure, edema, enlarged liver), 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),
- You are elderly (you are more likely to have severe side effects),
- you have kidney and liver problems,
- You have blood clotting problems,
- You have low blood volume (caused by bleeding or severe dehydration),
- You have problems with the blood vessels anywhere in your body,
- You have an autoimmune condition (in which the body's defense system tries to destroy the body) such as ulcerative colitis (inflammation of the bowel) or Crohn's disease (condition causing inflammation of the bowel, abdominal disease, diarrhea, vomiting, and weight loss),

If these warnings apply or applied to you, please consult your physician.

Using TROCMETAM with foods and drinks:

TROCMETAM can be used with or without food.

Pregnancy

Please consult your physician or pharmacist before taking the drug.

Unless otherwise stated by your doctor, do not use TROCMETAM if you are pregnant or you may be pregnant. Do not use TROCMETAM if you are in the last 3 months of pregnancy.

TROCMETAM may make it more difficult to become pregnant. Therefore, you should tell your doctor if you have problems becoming pregnant or you are being checked for infertility.

If you realize that you are pregnant during your treatment, immediately consult your physician or pharmacist.

Lactation

Please consult your physician or pharmacist before taking the drug.

Do not use TROCMETAM during breastfeeding, unless otherwise prescribed by your doctor.

Driving and using machines

Do not drive or operate machines as TROCMETAM may cause side effects such as dizziness, drowsiness or visual impairment which may affect driving and using machinery.

Important information about some of the excipients contained in TROCMETAM

This medicinal product contains less than 1 mmol (23 mg) sodium per ml, i.e it is essentially "sodium free".

This medicinal product contains sodium metabisulfite. This excipient can rarely cause severe hypersensitivity reactions and bronchospasm (narrowing of the bronchi).

Use in combination with other drugs

Tell your doctor or pharmacist if you are taking any of the following medicines while using TROCMETAM:

- Salicylate, ibuprofen, diclofenac or other NSAIDs,
- Cardiac glycosides used in heart failure (such as digoxin),
- A steroid such as hydrocortisone, prednisolone and dexamethasone (used in the treatment of edema and inflammation),
- Drugs that inhibit blood clotting such as warfarin, fenprocumone and heparin (antithrombotic drugs),
- Selective serotonin reuptake inhibitors and lithium (drugs used in the treatment of depression),
- Methotrexate (a drug used in skin problems, joint inflammation and cancer treatment),
Mifepristone (a drug used to terminate pregnancy),
- Cyclosporine and tacrolimus (immunosuppressive drugs),
- A "quinolone antibiotic" such as ciprofloxacin or moxifloxacin (an antibiotic group used in the treatment of infection),
- ACE inhibitors acting on the renin angiotensin system (eg, silazapril, enalapril) or ARBs (receptor blockers), other drugs used for the treatment of high blood pressure such as propranolol, which is a non-selective beta blocker drug,
- Zidovudine (a drug used in the treatment of AIDS),

- Diuretic drugs used in the treatment of high blood pressure, such as hydrochlorothiazide, furosemide,
- Oral drugs used for the prevention of diabetes (such as glibornuride, glibenclamide and tolbutamide),
- Probenecid used to treat gout,
- Drugs used to reduce gastric acid (antacids and cimetidine),
- Alcohol

If you are currently taking or recently took any prescribed or over-the-counter drugs, please inform your physician or pharmacist.

3. How to take TROCMETAM?

Instructions for proper use and dosage/administration frequency:

The dose of TROCMETAM varies from patient to patient. Your doctor will determine the dose of your medicine according to your age and depending your response to drug and will apply it to you.

Route and method of administration:

TROCMETAM is administered by your doctor into a vein or muscle.

When necessary treatment should be initiated with I.V or I.M. single daily dose for one to two days, to be continued with the oral or rectal tenoxicam.

Various age groups:

Use in children:

TROCMETAM should not be used in children.

Use in elderly:

Your doctor will determine the dosage of your drug depending on your illness and will apply it to you.

Special usage cases:

Renal failure

The above dosage recommendations also apply to patients suffering from kidney disease. However, when TROCMETAM is used in patients with renal failure, careful monitoring of renal function is recommended. It should not be used in patients with severe renal impairment.

Hepatic failure

The above dosage recommendations also apply to patients suffering from liver disease. However, when TROCMETAM is used in patients with liver failure, careful monitoring of hepatic function is recommended. It should not be used in patients with severe liver impairment.

If you are under the impression that the effect TROCMETAM is too strong or weak, consult your physician or pharmacist.

If you use more TROCMETAM than you should

As you will be given TROCMETAM by a doctor or a nurse, it is unlikely that you would use more or less than prescribed. However, please contact your doctor or nurse if you are not sure.

If you have used TROCMETAM more than you should have or more than prescribed, consult a physician or a pharmacist.

If you forget to take TROCMETAM:

As you will be given TROCMETAM by a doctor or a nurse, it is unlikely that you would miss a dose.

Do not double-dose to make up for forgotten doses.

Possible effects once TROCMETAM treatment is concluded

Do not stop using TROCMETAM without consulting your doctor.

4. Possible side effects

Like all medicines TROCMETAM may cause side effects in patients sensitive to its ingredients.

If any of the following reactions happen stop of the taking TROCMETAM and tell your doctor immediately or contact the casualty department at your nearest hospital:

- Allergic reactions including sudden swelling of your throat, face, hands or feet, difficulty breathing, swallowing and skin rashes, desquamation and itching
- Bleeding from the stomach, seen as vomit which has blood in it, or bits that look like coffee grounds.
- Bleeding of your intestines, seen as passing black sticky bowel motions or bloody diarrhea
- Ulcers in your stomach and gut; stomach pain, fever, nausea or vomiting
- 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, diarrhea, vomiting and weight loss.
- A severe skin reaction that develops quickly, with peeling of your skin, mouth and eyes
- Liver problems with yellowing of your skin or the whites of your eyes, feeling tired, loss of appetite, nausea and pale coloured stools and hepatitis (shown in blood tests).
- Heart attack with chest pain which may spread to your neck and shoulders and down your left arm.
- Stroke with muscle weakness and numbness which may only be on one side of your body, a suddenly altered sense of smell, taste, hearing or vision, confusion.

- Meningitis with fever, fatigue, nausea, stiff neck, headache, sensitivity to bright light and confusion.

These are all very serious side effects.

If you have any of the above, it means that you are allergic to TROCMETAM. You may need urgent medical attention or to be hospitalized.

If you notice any of the following side effects, tell your doctor or consult the nearest emergency room:

- Heartburn, indigestion, stomach pain, nausea, constipation, diarrhea, flatulation
- Blood problems such as anemia or change in white blood cell count
- Increased blood sugar (hyperglycemia)
- Difficulty sleeping and changes in your patterns of dreaming
- Depression
- Possibly seeing or hearing things that are not there (hallucination)
- Confusion or nervousness
- Headache
- Dizziness, sleepiness
- Tingling or numbness of the hands and feet
- Visual impairment, swollen or irritated eyes
- Ringing in the ears (Tinnitus)
- Vertigo
- Swelling in the hands, feet and legs (edema) Chest pain with tiredness and shortness of breath (heart failure)
- Palpitation, slowing heart beat or high blood pressure
- Problems with the way your heart pumps blood around the body; signs may include tiredness, shortness of breath, feeling faint, general pain
- Shortness of breath, wheezing and cough
- Itching, skin rash, sensitivity to the sun, hair loss (alopecia)
- Changes in nails
- Kidney problems
- Pain and ulcers of the mouth
- Loss of appetite
- Weight increase or decrease
- Difficulty to conceive
- Nose bleeding

These are severe side effects and may required immediate medical response.

If you notice any side effect not mentioned in this leaflet, please inform your doctor or pharmacist.

5. How to store TROCMETAM?

Keep TROCMETAM out of the sight and reach of children, and in its original packaging.

Use in compliance with the expiry date.

Store at temperature below 25°C. Use immediately after reconstitution.

Shake/swirl until product is completely dissolved during reconstitution.

Do not use TROCMETAM after the expiry date which is stated on the packaging.

Do not use TROCMETAM if you notice defects on the product and/or its packaging.

Do not throw away drugs that have expired or are not used! Deliver to the collection system determined by the local regulations.

Marketing Authorization Holder:

POLİFARMA İLAÇ SAN. VE TİC. A.Ş.
Vakıflar OSB Mahallesi, Sanayi Caddesi,
No:22/1, Ergene/Tekirdağ/TURKEY
Tel: +90 282 675 14 04, Fax: +90 282 675 14 05

Manufacturing Site (vial):

AROMA İLAÇ SANAYİ LTD. ŞTİ.
Vakıflar OSB Mahallesi, Sanayi Caddesi,
No:22/1 Kat:2, Ergene/Tekirdağ/TURKEY
Tel: +90 282 675 10 06, Fax: +90 282 675 14 05

Manufacturing Site (solvent ampoule):

AROMA İLAÇ SANAYİ LTD. ŞTİ.
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