

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

^{Pr}Ketorolac Tromethamine Injection USP

Ketorolac Tromethamine Injection

Read this carefully before you start taking **Ketorolac Tromethamine Injection USP** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Ketorolac Tromethamine Injection USP**.

Serious Warnings and Precautions

Heart and blood vessel problems:

- Ketorolac Tromethamine Injection USP can cause heart and blood vessel problems like heart attacks, stroke, blood clots, high blood pressure and heart failure. These can lead to death.
- The risk of having heart problems is higher if you take Ketorolac Tromethamine Injection USP for long periods of time and / or at higher doses and / or in people who have heart disease.
- Tell your healthcare professional if you have or had heart attacks, chest pain, heart disease, stroke, heart failure, high blood pressure or diabetes.

Stomach and intestine (gastrointestinal) problems:

- Ketorolac Tromethamine Injection USP can cause stomach and intestine problems like ulcers, inflammation, bleeding, holes / perforation, blockage or pain.

Talk to your healthcare professional about any medical conditions you have and medicines you are taking.

Pregnancy

- **DO NOT** take Ketorolac Tromethamine Injection USP if you are pregnant and in a later stage of pregnancy (28 weeks or later).
- If you are pregnant and in an earlier stage of pregnancy (less than 28 weeks) **only** take Ketorolac Tromethamine Injection USP if you are told to do so by your healthcare professional.
- Medicines like Ketorolac Tromethamine Injection USP may cause harm to you and your baby. Your healthcare professional will need to closely monitor your health

and that of your baby (including your amniotic fluid levels) if they prescribe Ketorolac Tromethamine Injection USP during this time.

- Tell your healthcare professional **right away** if you become pregnant, think you may be pregnant or want to get pregnant during your treatment with Ketorolac Tromethamine Injection USP.

What is Ketorolac Tromethamine Injection USP used for?

Ketorolac Tromethamine Injection USP is used in adults to relieve moderate to severe pain, usually after surgery. Ketorolac Tromethamine Injection USP will be given to you in a hospital or medical office for no more than 2 days.

How does Ketorolac Tromethamine Injection USP work?

- Ketorolac Tromethamine Injection USP belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). It can reduce the chemicals produced by your body which cause pain and swelling.
- Ketorolac Tromethamine Injection USP only treats the symptoms and relieves pain and inflammation as long as you take it. Ketorolac Tromethamine Injection USP does not cure the illness or stop it from getting worse.

What are the ingredients in Ketorolac Tromethamine Injection USP?

Medicinal ingredient: Ketorolac tromethamine

Non-medicinal ingredients: 10% (w / v) ethyl alcohol (preservative), sodium chloride (for tonicity), sodium hydroxide and/or hydrochloric acid (pH adjusters), and water for injection.

Ketorolac Tromethamine Injection USP comes in the following dosage forms:

Solution for injection: 30 mg / mL

Do not use Ketorolac Tromethamine Injection USP if you:

- have heart bypass surgery (planning to have or recently had).
- are pregnant and in a later stage of pregnancy (28 weeks or later).
- are in labour or giving birth.
- are currently breastfeeding (or planning to breastfeed).
- have severe, uncontrolled heart failure.
- are allergic to ketorolac tromethamine or any other ingredients in Ketorolac Tromethamine Injection USP or the container.
- have a history of asthma, hives, growths in your nose, sinus swelling or symptoms of an

allergic reaction after taking acetylsalicylic acid (ASA) or other NSAIDs.

- have active stomach or intestinal ulcers.
- have active bleeding from the stomach or gut.
- have inflammatory bowel disease (Crohn's Disease or Ulcerative Colitis).
- have bleeding in the brain or other bleeding disorders.
- have liver disease (active or severe).
- have kidney disease (moderate, severe or worsening).
- have high potassium in the blood.
- are going to have any major surgery.
- are taking:
 - other NSAIDs, used to treat pain, fever and inflammation.
 - probenecid, used to treat gout.
 - pentoxifylline (also known as oxpentifylline), used to improve blood circulation.
- are under 18 years of age.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Ketorolac Tromethamine Injection USP. Talk about any health conditions or problems you may have, including if you:

- have a condition that makes you frail or weak.
- have high cholesterol.
- have or had heart attacks, chest pain, heart disease, stroke or heart failure.
- have poor blood flow to your extremities (like your hands and feet).
- smoke or used to smoke.
- have liver or kidney problems, urine problems or are dehydrated.
- are on a low-salt diet.
- have a history of ulcer or bleeding from the stomach or gut (small or large intestines).
- drink a lot of alcohol.
- have a stomach infection.
- have asthma.
- have other bleeding or blood problems.
- have immune system problems.
- are pregnant, planning on becoming or become pregnant while taking Ketorolac Tromethamine Injection USP.
- are taking any other medicines.

Other warnings you should know about:

Ketorolac Tromethamine Injection USP may cause serious side effects, including:

- **Blood and bleeding problems:**
 - Ketorolac Tromethamine Injection USP can cause blood problems, bleeding

and prolonged bleeding.

- Taking Ketorolac Tromethamine Injection USP with the following medicines can increase the risk of bleeding:
 - anticoagulants (prevents blood clots), corticosteroids (anti-inflammatory), or antidepressants like selective serotonin reuptake inhibitors (SSRIs).
- **Aseptic meningitis** (inflammation of the protective lining of the brain that is not caused by an infection): Patients with autoimmune disorders are at a higher risk.
- **Serious skin reactions:** In rare cases, serious, life-threatening allergic and skin reactions have been reported with some NSAIDs, such as Ketorolac Tromethamine Injection USP. These skin problems most often happen during the first month of treatment. Tell your healthcare professional immediately if you notice any changes in your skin both during and after treatment.

Ketorolac Tromethamine Injection USP might cause you to become more sensitive to sunlight. Sunlight or sunlamps may cause sunburn, skin blisters, skin rash, redness, itching or discoloration, or vision changes. If you have a reaction from the sun, talk to your healthcare professional.

See the **Serious side effects and what to do about them** table for more information on these and other serious side effects.

Infection: Ketorolac Tromethamine Injection USP may mask signs of an infection such as fever or muscle aches. If you notice other symptoms of infection (e.g., painful or frequent urination, sore throat, cough), tell your healthcare professional.

Wound bleeding: Ketorolac Tromethamine Injection USP may cause your wound to bleed after surgery. Tell your healthcare professional if you notice painful swelling, bruising, lumps or active bleeding from your wound after you are given Ketorolac Tromethamine Injection USP.

Surgery: Tell all your doctors, dentists, pharmacists or healthcare professionals that you are taking this medicine. This is especially important if you are planning to have heart surgery.

Fertility in women: Ketorolac Tromethamine Injection USP may affect your fertility. This means that it may be difficult for you to have a child. If you have trouble having a child, you might need to stop taking Ketorolac Tromethamine Injection USP. Talk to your healthcare professional if you have any questions about this.

Patients-65 years of age or older: Side effects like gastrointestinal problems may happen more often. Your healthcare professional might have you start with a lower dose of Ketorolac Tromethamine Injection USP. They will monitor your health during and after treatment.

Driving and using machinery: Ketorolac Tromethamine Injection USP may cause eye or nervous system problems. This includes tiredness, trouble sleeping, blurred vision, spinning or dizziness (vertigo), hearing problems or depression. Be careful about driving or doing activities that require you to be alert. If you become drowsy, dizzy or light-headed after taking Ketorolac Tromethamine Injection USP, do NOT drive or operate machinery.

Check-ups and testing: You will have regular visits with your healthcare professional during treatment with Ketorolac Tromethamine Injection USP to monitor your health. They will:

- Check your blood pressure.
- Check your eyes. Ketorolac Tromethamine Injection USP can cause blurred or reduced vision.
- Do blood and urine tests to check your liver, kidney and blood health.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Serious Drug Interactions

Do not take Ketorolac Tromethamine Injection USP with:

- acetylsalicylic acid (ASA) or other NSAIDs, used to treat pain, fever and inflammation (e.g., celecoxib, diclofenac, ibuprofen, indomethacin, ketorolac, meloxicam, naproxen);
- pentoxifylline (also known as oxpentifylline), used to improve blood circulation;
- probenecid, used to treat gout.

Taking Ketorolac Tromethamine Injection USP with these medicines may cause serious drug interactions. Ask your healthcare professional if you are unsure you are taking these medicines.

The following may also interact with Ketorolac Tromethamine Injection USP:

- antacids, used to treat symptoms of excess stomach acid.
- medicines used to treat depression (antidepressants), like citalopram, fluoxetine, paroxetine, sertraline, and lithium.
- medicines used to treat high blood pressure, like enalapril, lisinopril,

perindopril, ramipril, candesartan, irbesartan, losartan, valsartan, and propranolol.

- medicines used to lower extra fluid levels (diuretics), like furosemide, and hydrochlorothiazide.
- medicines used as blood thinners or to prevent blood clots, like warfarin, ASA, clopidogrel, heparin, and dextrans.
- cyclosporine and tacrolimus, used to lower the risk of organ transplant rejection.
- methotrexate and pemetrexed, used to treat different cancers.
- digoxin, used to treat heart disorders.
- corticosteroids, used to treat inflammation, like glucocorticoids such as prednisone.
- medicines used to treat seizures or epilepsy (antiepileptics), like phenytoin and carbamazepine.
- mifepristone, used for abortions. Ketorolac Tromethamine Injection USP should not be used for 8-12 days after taking mifepristone.
- medicines used to treat muscle spasms and back pain (muscle relaxants).
- opioids, used to relieve pain.
- thiothixene, used to treat schizophrenia.
- alprazolam, used to manage symptoms of anxiety.
- medicines used to treat certain bacterial infections (antibiotics), like aminoglycosides and quinolone antibiotics.
- zidovudine, used to prevent and treat human immunodeficiency virus (HIV).
- alcohol.

How to take Ketorolac Tromethamine Injection USP:

- Ketorolac Tromethamine Injection USP will be given to you by a healthcare professional in a hospital or medical office. It is usually given for no more than 2 days.
- You will receive Ketorolac Tromethamine Injection USP into your muscle (i.e., “intramuscularly” or “IM”).
- The dose given to you will depend on the severity of your pain. Your healthcare professional will give you the lowest dose possible for your treatment for the shortest time needed.
- Tell your healthcare professional if you notice any side effects while receiving this medicine. They may change your dose depending on your response to Ketorolac Tromethamine Injection USP.
- Your healthcare professional may prescribe you ketorolac tromethamine tablets to take by mouth during or following your treatment with Ketorolac Tromethamine Injection USP. Take them as directed by your healthcare professional.

Usual dose:

Your healthcare professional will decide the right dose for you.

Overdose:

Signs of an overdose with Ketorolac Tromethamine Injection USP may include:

- nausea or vomiting;
- abnormally fast, slow or deep breathing;
- abdominal pain, ulcer or bleeding from the stomach or gut;
- kidney problems;
- high blood pressure;
- coma.

If you think you, or a person you are caring for, have been given too much Ketorolac Tromethamine Injection USP, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed Dose:

If a dose is missed, the dose will be given to you by your healthcare professional as soon as it is recognized. The regular dosing schedule will be continued thereafter. You will not receive two doses at the same time to make up for the missed dose.

What are possible side effects from using Ketorolac Tromethamine Injection USP?

These are not all the possible side effects you may have when taking Ketorolac Tromethamine Injection USP. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- Nausea, vomiting, diarrhea, constipation, stomach upset, heartburn, indigestion, or feeling gassy;
- Headache, dizziness, or light-headedness;
- Feeling tired, trouble sleeping, or abnormal dreams;
- Feeling of burning or prickling of the skin;
- Inability to concentrate, anxiety, or nervousness;
- Thirst, dry mouth, sore throat, or changes in tastes;
- Bruises, or rash;

- Muscle pain / twitching;
- Mouth sores;
- Increased sweating;
- Pain at injection site;

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Gastrointestinal (GI) problems (bleeding, blockage, holes, ulcers or inflammation in your GI tract): blood in vomit, black tarry or bloody stool, dizziness, stomach pain, bloating, loss of appetite, weight loss, nausea, vomiting, constipation or diarrhea, chills or fever		✓	
Hypertension (high blood pressure): fatigue, dizziness or fainting, chest pain	✓		
UNCOMMON			
Anaphylaxis / hypersensitivity (severe allergic reactions): sudden wheeziness and chest pain or tightness; or swelling of eyelids, face, lips, tongue or throat, swelling or anaphylactic reaction / shock			✓
Aseptic meningitis (inflammation of the protective lining of the brain that is not caused by infection): Headaches, stiff neck, nausea and vomiting, fever or clouding of consciousness		✓	
Blood problems (low white and / or red blood		✓	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
cell or platelet count): feeling tired or weak, pale skin, bruising or bleeding for longer than usual if you hurt yourself, fever, chills			
Congestive heart failure (heart does not pump blood as well as it should): shortness of breath, fatigue and weakness, swelling in ankles, legs and feet, cough, fluid retention, lack of appetite, nausea, rapid or irregular heartbeat, reduced ability to exercise			✓
Cystitis (bladder infection): increased need to urinate, pain in the pelvis or lower back, frequent urination during the night, cloudy urine that may contain blood, burning or pain urinating		✓	
Depression (sad mood that will not go away): difficulty sleeping or sleeping too much, changes in appetite or weight, reduced sex drive and thoughts of death or suicide.		✓	
Kidney disorder / problems (including kidney failure and renal papillary necrosis) : nausea, vomiting, fever, swelling of extremities, fatigue, thirst, dry skin, irritability, dark urine, increased or decreased urine output, blood in the urine, rash, weight gain (from retaining fluid), loss		✓	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
of appetite, mental status changes (drowsiness, confusion, coma), painful urination, chills, back pain			
Liver problems (including hepatitis, liver failure, cholestasis): yellowing of your skin and eyes (jaundice), right upper stomach area pain or swelling, nausea or vomiting, unusual dark urine, unusual tiredness		✓	
Lung problems (including asthma): increased shortness of breath, wheezing, difficulty breathing, cough, chest tightness, irregular heartbeat, chest pain, fever.			✓
Myocardial infarction (heart attack): pressure or squeezing pain between the shoulder blades, in the chest, jaw, left arm or upper abdomen, shortness of breath, dizziness, fatigue, light-headedness, clammy skin, sweating, indigestion, anxiety, feeling faint and possible irregular heartbeat.			✓
Stroke (bleeding or blood clot in the brain): sudden numbness, weakness or tingling of the face, arm, or leg, particularly on one side of the body, sudden headache, blurry vision, difficulty swallowing or speaking, or lethargy, dizziness,			✓

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
fainting, vomiting, trouble understanding, trouble with walking and loss of balance			
Tinnitus (hearing problems): includes ringing, buzzing, clicking or hissing in ears, loss of hearing		✓	
Vertigo (a sense of severe spinning dizziness, light-headedness)		✓	
RARE			
Serious Skin Reactions: fever, severe rash, swollen lymph glands, flu-like feeling, blisters and peeling skin that may start in and around the mouth, nose, eyes and genitals and spread to other areas of the body, swelling of face and / or legs, yellow skin or eyes, shortness of breath, dry cough, chest pain or discomfort, feeling thirsty, urinating less often, less urine or dark urine, hives, red or dry itchy skin, purple or red spots on skin			✓
UNKNOWN FREQUENCY			
Eye problems: blurred vision, loss of part or all of central vision, reduced color vision, dimness of vision.		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Store Ketorolac Tromethamine Injection USP between 20°C and 25°C. Protect from light and freezing. Discard unused portion.
- Keep out of reach and sight of children.

If you want more information about Ketorolac Tromethamine Injection USP:

- Talk to your healthcare professional.
- Find the full Product Monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website <https://www.pfizer.ca/>, or by calling 1-800-463-6001.

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