

PART III: CONSUMER INFORMATION**^{Pr}Ketorolac Tromethamine Injection USP
30 mg/mL**

This leaflet is part III of a three-part "Product Monograph" published when Ketorolac Tromethamine Injection USP was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about Ketorolac Tromethamine Injection USP. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION**What the medication is used for:**

Your health care provider has prescribed Ketorolac Tromethamine Injection USP for you for one or more of the following medical conditions:

- for short-term use in the hospital for pain relief after surgery (not to exceed 2 days)

What it does:

Ketorolac Tromethamine Injection USP, as a non-steroidal anti-inflammatory drug (NSAID), can reduce the chemicals produced by your body which cause pain and swelling.

Ketorolac Tromethamine Injection USP, as a non-steroidal anti-inflammatory drug (NSAID), does NOT cure your illness or prevent it from getting worse. Ketorolac Tromethamine Injection USP only can relieve pain and reduce swelling as long as you continue to take it.

When it should not be used:

DO NOT TAKE Ketorolac Tromethamine Injection USP if you have any of the following medical conditions:

- have had or are planning to have heart bypass surgery
- have severe, uncontrolled heart failure
- have bleeding in the brain or other bleeding disorders
- are at 28 weeks of pregnancy or more
- are in labour and delivery
- are breastfeeding or planning to breastfeed
- are allergic to ASA (Acetylsalicylic Acid), other NSAIDs (Non-steroidal Anti-Inflammatory Drugs), Ketorolac Tromethamine Injection USP or its ingredients
- have active ulcer or bleeding from the stomach or gut
- have inflammatory bowel disease (Crohn's Disease or Ulcerative Colitis)
- have liver or kidney disease
- have high potassium in the blood
- are currently using probenecid or oxpentifylline
- are having central nervous system injection e.g. epidural, brain or spinal administration
- are going into have any major surgery
- are using other NSAIDs

Patients who took a drug in the same class as Ketorolac Tromethamine Injection USP after a type of heart surgery (coronary artery bypass grafting (CABG)) were more likely to have heart attacks, strokes, blood clots in the leg(s) or lung(s), and infections or other complications than those who did NOT take that drug.

Ketorolac Tromethamine Injection USP should NOT be used in patients under 18 years of age since the safety and effectiveness have NOT been established.

What the medicinal ingredient is:

Ketorolac tromethamine

What the non-medicinal ingredients are:

10% (w/v) ethyl alcohol, sodium chloride, sodium hydroxide, hydrochloric acid, water for injection.

What dosage forms it comes in:

Ketorolac Tromethamine Injection USP is available as: solution for intramuscular injection (30 mg/mL).

WARNINGS AND PRECAUTIONS

If you have, or previously had, any of the following medical conditions, see your health care provider to discuss treatment options other than Ketorolac Tromethamine Injection USP:

- Heart Attack or Angina
- Stroke or Mini-stroke
- Loss of Vision
- Current Pregnancy (less than 28 weeks)
- Congestive Heart Failure

BEFORE taking this medication, tell your health care provider if you have any of the following:

- High blood pressure
- High cholesterol
- Diabetes mellitus or on a low sugar diet
- Thickening or hardening of your artery walls (Atherosclerosis)
- Poor circulation to your extremities
- Smoker or ex-smoker
- Kidney disease or urine problems
- Previous ulcer or bleeding from the stomach or gut
- Previous bleeding in the brain
- Bleeding problems
- Liver, biliary, pancreatic or renal problems
- Family history of allergy to NSAIDs, such as acetylsalicylic acid (ASA), celecoxib, diclofenac, diflunisal, etodolac, fenoprofen, flurbiprofen, ibuprofen, indomethacin, ketoprofen, ketorolac, mefenamic acid, meloxicam, nabumetone, naproxen, oxaprozin, piroxicam, rofecoxib, sulindac, tenoxicam, tiaprofenic acid, tolmetin, or valdecoxib (NOT a complete list)

- Family history of asthma, nasal polyps, long-term swelling of the sinus (chronic sinusitis) or hives
- Family history of allergy to sulfonamide drugs (if applicable)
- Any other medical problem

Also, before taking this medication, tell your health care provider if you are planning to get pregnant.

While taking this medication:

- tell any other doctor, dentist, pharmacist or other health care professional that you see, that you are taking this medication, especially if you are planning to have heart surgery;
- do NOT drink alcoholic beverages while taking this medication because you would be more likely to develop stomach problems;
- fertility may be decreased. The use of Ketorolac Tromethamine Injection USP is not recommended in women trying to get pregnant. In women who have difficulty conceiving, stopping Ketorolac Tromethamine Injection USP should be considered.

INTERACTIONS WITH THIS MEDICATION

Talk to your health care provider and pharmacist if you are taking any other medication (prescription or non-prescription) such as any of the following (NOT a complete list):

- Acetylsalicylic Acid (ASA) or other NSAIDs
 - e.g. ASA, celecoxib, diclofenac, ibuprofen, indomethacin, ketorolac, meloxicam, naproxen)
- Antacids
- Antidepressants
 - Selective Serotonin Reuptake Inhibitors (SSRIs)
 - e.g. citalopram, fluoxetine, paroxetine, sertraline
- Blood pressure medications
 - ACE (angiotensin converting enzyme) inhibitors
 - e.g. enalapril, lisinopril, perindopril, ramipril
 - ARBs (angiotensin II receptor blockers)
 - e.g. candesartan, irbesartan, losartan, valsartan
- Blood thinners
 - e.g. warfarin, ASA, clopidogrel
- Corticosteroids (including glucocorticoids)
 - e.g. prednisone
- Cyclosporin
- Digoxin
- Diuretics
 - e.g. furosemide, hydrochlorothiazide
- Lithium
- Methotrexate
- Morphine
- Oxpentifylline
- Probenacid

Your health care provider may prescribe low dose ASA (acetylsalicylic acid) as a blood thinner to reduce your risk of

having a heart attack or stroke while you are taking Ketorolac Tromethamine Injection USP.

Take only the amount of ASA prescribed by your health care provider. You are more likely to upset or damage your stomach if you take both Ketorolac Tromethamine Injection USP and ASA than if you took Ketorolac Tromethamine Injection USP alone.

PROPER USE OF THIS MEDICATION

Usual dose:

Usual dose (18-65 years of age):

Medical Condition	Starting Dose	Maximum Dose (per day)	Maximum Duration of Treatment (days)
Post-surgical or Musculo-skeletal Pain	Initial dose: 10 mg to 30 mg according to pain. Subsequent doses: 10 mg to 30 mg every 4 to 6 hours as needed to control pain	Doses exceeding 120 mg per day are not recommended	2 days

Take Ketorolac Tromethamine Injection USP only as directed by your health care provider. **Do NOT take more of it, do NOT take it more often and do NOT take it for a longer period of time than your health care provider recommended. If possible, you should take the lowest dose of this medication for the shortest time period.**

Taking too much Ketorolac Tromethamine Injection USP may increase your chances of unwanted and sometimes dangerous side effects, especially if you are elderly, have other diseases or take other medications.

In general, Ketorolac Tromethamine Injection USP should not be used for more than 2 days.

This medication has been prescribed specifically for you. Do NOT give it to anyone else. It may harm them, even if their symptoms seem to be similar to yours.

Ketorolac Tromethamine Injection USP is NOT recommended for use in patients under 18 years of age since safety and effectiveness have NOT been established.

Missed Dose:

The missed dose should be taken as soon as remembered, and then the regular dosing schedule should be continued. Two doses of Ketorolac Tromethamine Injection USP should not be taken at the same time.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Ketorolac Tromethamine Injection USP may cause some side effects, especially when used for a long time or in large doses. When these side effects occur, you may require medical attention. Report all symptoms or side effects to your health care provider.

Ketorolac Tromethamine Injection USP may cause you to become drowsy or tired. Be careful about driving or participating in 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.

Ketorolac Tromethamine Injection USP may cause you to become more sensitive to sunlight. Any exposure to sunlight or sunlamps may cause sunburn, skin blisters, skin rash, redness, itching or discolouration, or vision changes. If you have a reaction from the sun, check with your health care provider.

Check with your health care provider IMMEDIATELY if you develop chills, fever, muscle aches or pains, or other flu-like symptoms, especially if they occur before or together with a skin rash. These symptoms may be the first signs of a SERIOUS ALLERGIC REACTION to this medication.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom	STOP taking drug and get emergency medical attention IMMEDIATELY	STOP taking drug and seek immediate emergency medical attention
Bloody or black tarry stools	✓	
Shortness of breath, wheezing, any trouble breathing or chest tightness	✓	
Skin rash, hives, swelling or itching	✓	
Blurred vision, or any visual disturbance	✓	
Any change in the amount or colour of your urine (red or brown)	✓	
Any pain or difficulty experienced while urinating		✓
Swelling of the feet, lower legs, weight gain		✓
Vomiting or persistent indigestion, nausea, stomach pain or diarrhea		✓

Yellow discolouration of the skin or eyes, with or without itchy skin		✓
Malaise, fatigue, loss of appetite		✓
Headaches, stiff neck		✓
Mental confusion, depression		✓
Dizziness, lightheadedness		✓
Hearing problems		✓

This is not a complete list of side effects. For any unexpected effects while taking Ketorolac Tromethamine Injection USP, contact your doctor or pharmacist.

HOW TO STORE IT

Store Ketorolac Tromethamine Injection USP between 20°C and 25°C. Protect from light and freezing. Discard unused portion.

Do NOT keep outdated medicine or medicine no longer needed. Any outdated or unused medicine should be returned to your pharmacist

Keep out of sight and reach of children.

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](https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

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

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found by contacting the sponsor, Pfizer Canada Inc. at **1-800-463-6001**.

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