

## PRODUCT MONOGRAPH

**Pr**TORADOL<sup>®</sup>

ketorolac tromethamine  
10 mg tablets

**Pr**TORADOL<sup>®</sup> IM

ketorolac tromethamine injection  
10 mg/mL intramuscular injection

Non-Steroidal Anti-Inflammatory Drug (NSAID)

Hoffmann-La Roche Limited  
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**Pr TORADOL®**  
ketorolac tromethamine tablets

**Pr TORADOL® IM**  
ketorolac tromethamine injection

Read this information each time you refill your prescription in case new information has been added.

This leaflet is part III of a three-part "Product Monograph" published when TORADOL was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary designed specifically for you. It will not tell you everything about TORADOL. See your health care provider and pharmacist regularly and ask them questions about your health and any medications you take.

**TORADOL 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 TORADOL 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.

TORADOL 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:**

**TORADOL tablets:** microcrystalline cellulose, lactose, magnesium stearate, hydroxy-propyl-methylcellulose, titanium dioxide, polyethylene glycol, edible black printing ink.

**TORADOL IM:** 10% (w/v) alcohol, sodium chloride, sodium hydroxide, hydrochloric acid.

**What dosage forms it comes in:**

TORADOL is available as: tablets (10 mg) and solution for intramuscular injection (10 mg/mL).

**ABOUT THIS MEDICATION**

**What the medication is used for:**

**Toradol Tablets**

Your health care provider has prescribed TORADOL tablets for you for one or more of the following medical conditions:

- for short-term use as pain relief after surgery, after labour or after injury causing muscle or joint pain (not to exceed 5 days for post-surgical patients or 7 days for patients with musculoskeletal pain)

**Toradol Intramuscular Injection**

Your health care provider has prescribed TORADOL IM 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:**

TORADOL (ketorolac tromethamine), as a non-steroidal anti-inflammatory drug (NSAID), can reduce the chemicals produced by your body which cause pain and swelling.

TORADOL, as a non-steroidal anti-inflammatory drug (NSAID), does NOT cure your illness or prevent it from getting worse.

TORADOL only can relieve pain and reduce swelling as long as you continue to take it.

**When it should not be used:**

**DO NOT TAKE TORADOL** 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),

**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 TORADOL:**

- 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 TORADOL is not recommended in women trying to get pregnant. In women who have difficulty conceiving, stopping TORADOL should be considered.

- 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 TORADOL. 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 TORADOL and ASA than if you took TORADOL alone.

**PROPER USE OF THIS MEDICATION**

**TORADOL Tablets**

**Usual dose (18-65 years of age):**

Medical Condition	Starting Dose	Maximum Dose (per day)	Maximum Duration of Treatment (days)
Post-Surgical Pain or post-partum uterine cramping pain	10 mg every 4 to 6 hours as required	Doses exceeding 40 mg per day are not recommended	5 days
Musculo-skeletal Pain	10 mg every 4 to 6 hours as required	Doses exceeding 40 mg per day are not recommended	7 days

**TORADOL IM**

**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 TORADOL 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 TORADOL may increase your chances of unwanted and sometimes dangerous side effects, especially if you

**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

are elderly, have other diseases or take other medications.

In general, TORADOL should not be used for more than 7 days. If a longer period is considered, see your health care provider regularly to discuss whether this medicine is working for you and if it is causing you any unwanted effects.

**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.**

**TORADOL is NOT recommended for use in patients under 18 years of age since safety and effectiveness have NOT been established.**

To lessen stomach upset, take TORADOL immediately after a meal or with food or milk. However, the presence of food in the stomach may delay the onset of pain relief. If stomach upset (indigestion, nausea, vomiting, stomach pain or diarrhea) occurs and continues, contact your doctor.

You should remain standing or sitting upright (i.e. do not lie down) for about 15-30 minutes after taking the medicine. This helps to prevent irritation that may lead to trouble swallowing.

**Missed Dose:**

The missed dose should be taken as soon as remembered, and then the regular dosing schedule should be continued. Two doses of TORADOL 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.

ALLERGIC REACTION to this medication.

<b>SERIOUS SIDE EFFECTS AND WHAT TO DO ABOUT THEM</b>		
<b>Symptom</b>	<b>STOP taking TORADOL and get emergency medical attention IMMEDIATELY</b>	<b>STOP taking TORADOL and talk to your physician or pharmacist</b>
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. If you develop any other symptoms while taking TORADOL, see your health care provider.

**HOW TO STORE IT**

Store TORADOL at room temperature (15-30° C) away from light.

**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.**

**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

TORADOL 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.

TORADOL 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 TORADOL, do NOT drive or operate machinery.

TORADOL 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

**REPORTING SUSPECTED SIDE EFFECTS**

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect)
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
  - Fax toll-free to 1-866-678-6789, or
  - Mail to: Canada Vigilance Program  
Health Canada  
Postal Locator 0701E  
Ottawa, Ontario  
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect).

*NOTE: Should you require information related to the management of side effects, contact your health professional. 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 at:

[www.rochecanada.com](http://www.rochecanada.com)

or by contacting the sponsor, Hoffmann-La Roche Limited, at: 1-888-762-4388 (Drug Information).

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