IMPORTANT: PLEASE READ

PART III: CONSUMER INFORMATION

PrVOLTAREN RAPIDE®
(diclofenac potassium)

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 PrVOLTAREN RAPIDE® was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about VOLTAREN RAPIDE. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the Medication is used for:

Your healthcare provider has prescribed VOLTAREN RAPIDE for short term treatment of acute, mild to moderately severe pain that may be accompanied with swelling (inflammation) in conditions such as sprains, tooth extraction, episiotomy (a surgical cut made just before delivery to enlarge vaginal opening), and dysmenorhea (painful menstrual periods).

What it does:

VOLTAREN RAPIDE (diclofenac potassium), as a nonsteroidal anti-inflammatory drug (NSAID), can reduce the chemicals prostaglandins produced by your body which cause pain and swelling.

VOLTAREN RAPIDE, as a nonsteroidal anti-inflammatory drug (NSAID) does NOT cure your illness or prevent it from getting worse. VOLTAREN RAPIDE can only relieve pain and reduce swelling as long as you continue to take it.

When it should not be used:

***DO NOT TAKE VOLTAREN RAPIDE* if you have any of the following conditions:**

- **Heart bypass surgery (planning to have or recently had)**
- **Severe, uncontrolled heart failure**
- **Bleeding in the brain or other bleeding disorders**
- **Currently pregnant and in a later stage of pregnancy (from 28 weeks or later)**
- **Currently breastfeeding (or planning to breastfeed)**
- **Allergy (hypersensitivity) to diclofenac potassium, or ASA (Acetylsalicylic Acid), or other NSAIDs (Nonsteroidal Anti-Inflammatory Drugs), or any of the nonmedicinal ingredients in VOLTAREN RAPIDE**
- **Ulcer (active)**
- **Bleeding or perforation from the stomach or gut (active)**
- **Inflammatory bowel disease (Crohn's Disease or Ulcerative Colitis)**
- **Liver disease (active or severe)**
- **Kidney problems (severe or worsening)**
- **High potassium in the blood**

Patients who took a drug in the same class as VOLTAREN RAPIDE 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.

VOLTAREN RAPIDE should NOT be used in patients under 16 years of age since the safety and effectiveness have NOT been established.

What the medicinal ingredient is:

VOLTAREN RAPIDE contains the active ingredient diclofenac potassium.

What the non-medicinal ingredients are:

Each VOLTAREN RAPIDE tablet contains the following inactive ingredients: cellulose, colloidal silicon dioxide, corn starch, ferric oxide, magnesium stearate, polyethylene glycol, povidone, sodium carboxymethyl starch, sucrose, talc, titanium dioxide and tribasic calcium phosphate.

What dosage forms it comes in:

VOLTAREN RAPIDE 50 mg (sugar coated) tablet: reddish brown, round, biconvex.

Check with your pharmacist if the identifying markings or colour appear different.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

If you have, or previously had, any of the following conditions, see your health care provider to discuss treatment options other than VOLTAREN RAPIDE.

- **Heart Attack or Angina**
- **Stroke or Mini-stroke**
- **Loss of Vision**
- **Current Pregnancy (less than 28 weeks)**
- **Congestive Heart Failure**
- **High blood pressure**
- **Diabetes**
- **High levels of fats in your blood**
- **Smoking**

It is important to take the lowest dose of VOLTAREN RAPIDE that relieves your pain and/or swelling and for the shortest time possible in order to keep your risk of side effects on the heart and blood vessels as small as possible.

Use of NSAIDS, such as VOLTAREN RAPIDE can result in increased blood pressure and/or worsening of congestive heart failure

Use of NSAIDs, such as VOLTAREN RAPIDE, may cause stomach and bowel problems (such as ulceration, perforation, obstruction and bleeding).

Pregnancy:
DO NOT take VOLTAREN RAPIDE 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 VOLTAREN RAPIDE if you are told to do so by your doctor. Medicines like VOLTAREN RAPIDE may cause harm to you and your baby. Your doctor will need to closely monitor your health and that of your baby (including your amniotic fluid levels) if they prescribe VOLTAREN RAPIDE during this time.

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

- Disease of the heart or blood vessels (also called cardiovascular disease, including uncontrolled high blood pressure, congestive heart failure, established ischemic heart disease, or peripheral arterial disease), as treatment with VOLTAREN RAPIDE in these cases is not recommended.
- Risk factors for cardiovascular disease (see above) such as high blood pressure, abnormally high levels of fat (cholesterol, triglycerides) in your blood, diabetes, or if you smoke,
- Diabetes mellitus or on a low sugar diet
- Atherosclerosis
- Poor circulation to your extremities
- Kidney disease or urine problems
- Previous ulcer or bleeding from the stomach or gut
- If you recently had a surgery of the stomach or intestinal tract (intestines, colon, rectum, anus).
- Previous bleeding in the brain
- Bleeding 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
- Any other medical problem such as alcohol abuse
- Any side effects from medicines for arthritis, rheumatism or sore joints that you have taken in the past
- A history of stomach upset
- Are on any special diet, such as a low-sodium diet

Also, before taking this medication, tell your health care provider if you are pregnant, planning on becoming pregnant or become pregnant while taking VOLTAREN RAPIDE.

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, or surgery of the stomach or intestinal tract;
- 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 VOLTAREN RAPIDE is not recommended in women trying to get pregnant. In women who have difficulty conceiving, stopping VOLTAREN RAPIDE should be considered.
- If you have cardiovascular disease or risks for cardiovascular disease, your doctor will periodically re-evaluate whether you should continue treatment with VOLTAREN RAPIDE.

- Your doctor will monitor your kidney function, your liver function and your blood count to decide if VOLTAREN RAPIDE needs to be discontinued.

If, at any time while taking VOLTAREN RAPIDE you experience any signs or symptoms of problems with your heart or blood vessels such as chest pain, shortness of breath, weakness, or slurring of speech, contact your doctor immediately.

Long-term use of VOLTAREN RAPIDE might increase the risk of heart attacks or strokes

Serious Skin Reactions: In rare cases, serious or life-threatening skin reactions listed below have been reported with some NSAIDs, such as VOLTAREN RAPIDE.
• Drug reaction with eosinophilia and systemic symptoms (DRESS)
• Stevens-Johnson syndrome (SJS),
• toxic epidermal necrolysis (TEN),
• exfoliative dermatitis and
• erythema multiforme

You may be at a greater risk of experiencing a serious skin reaction usually during the first month of treatment. See the Serious side effects and what to do about them table, below, for more information on these and other serious side effects.

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):

- Acetaminophen
- Acetylsalicylic Acid (ASA) or other NSAIDs
  e.g. ASA, celecoxib, diclofenac, ibuprofen, indomethacin, ketorolac, meloxicam, naproxen
- Alcohol
- Antacids
- Anti-depressants
  - 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
  - Beta-blockers
  e.g. metoprolol
- Blood thinners (medicines used to prevent blood clotting)
  e.g. warfarin, ASA, clopidogrel
- Corticosteroids (including glucocorticoids) (medicines used to provide relief for inflamed areas of the body)
  e.g. prednisone
- Cyclosporine (a medicine primarily used in patients who have received organ transplants)
- Digoxin (a medicine used for heart problems)
- Diuretics (medicines used to increase the amount of urine)
  e.g. furosemide, hydrochlorothiazide
- Lithium
- Methotrexate (a medicine used to treat some kinds of cancer or arthritis)
- Oral hypoglycemics (diabetes medications such as metformin)
- Phenytoin (a medicine used to treat seizures).
- Probenecid
- Quinolone antibacterials (medicines used against infection)
- Rifampin (an antibiotic medicine used to treat bacterial infections)
- Sulfinpyrazone (a medicine used to treat gout)
- Tacrolimus (a medicine primarily used in patients who have received organ transplants)
- Trimethoprim (a medicine used to prevent or treat urinary tract infection)
- Voriconazole (a medicine used to treat fungal infections).

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 VOLTAREN RAPIDE. 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 VOLTAREN RAPIDE and ASA than if you took VOLTAREN RAPIDE alone.

PROPER USE OF THIS MEDICATION

Usual dose:

Medical Condition	Usual Dose	Maximum Dose (per day)	Maximum Duration of Treatment
Pain and swelling	50 mg every 6-8 hours (if needed)	100 mg	One week

Painful menstrual cramps	First dose of 50 mg or (if needed) 100 mg followed by 50 mg every 6-8 hours after initial dose (if needed)	100 mg. First day may be increased to 200 mg	when required

Take VOLTAREN RAPIDE 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 VOLTAREN RAPIDE may increase your chances of unwanted and sometimes dangerous side effects, especially if you are elderly and frail or if you have a low body weight, have other diseases or take other medications.

If you are not getting adequate relief from your medication, speak to your doctor before you stop taking it.

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.

VOLTAREN RAPIDE is NOT recommended for use in patients under 16 years of age since safety and effectiveness have NOT been established.

Take the VOLTAREN RAPIDE with a meal or food to reduce the possibility of stomach upset.

VOLTAREN RAPIDE: VOLTAREN RAPIDE are immediate release tablets. The tablets should be swallowed whole with water, and must not be divided or chewed.

Missed dose:

If you forget to take one or more doses of VOLTAREN RAPIDE (diclofenac potassium), you should not increase the dose of VOLTAREN RAPIDE to make up for the missed dose or doses, but you should continue taking your tablet at the next prescribed or regular time.

Overdose:

If you have accidentally taken more than the prescribed dose of VOLTAREN RAPIDE, **contact your doctor, pharmacist or poison control centre immediately or go to the hospital emergency unit at once.** You may require medical attention.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

VOLTAREN RAPIDE 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.

VOLTAREN RAPIDE 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 VOLTAREN RAPIDE, do NOT drive or operate machinery.

VOLTAREN RAPIDE 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 AND WHAT TO DO ABOUT THEM

Symptom	**STOP taking VOLTAREN RAPIDE and get emergency medical attention IMMEDIATELY**	**STOP taking VOLTAREN RAPIDE and talk to your physician or pharmacist**
Bloody or black tarry stools, vomiting blood	√	
Spontaneous bleeding or bruising (signs of thrombo-cytopenia)	√	

Shortness of breath, wheezing, any trouble breathing or chest tightness	√	
Skin rash, hives, swelling or itching	√	
Skin rash with flacking or peeling (signs of dermatitis exfoliative).	√	
Purple skin patches (signs of purpura or Henoch-Schonlein purpura if caused by an allergy).	√	
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		√
Swelling mainly of the face, throat, lips, tongue, and/or extremities (signs of angioedema)		√
Vomiting or persistent indigestion, nausea, stomach pain or diarrhea		√
Chest pain and allergic reactions happening at the same time (signs of Kounis syndrome)	√	
Yellow discolouration of the skin or eyes (signs of liver failure), with or without itchy skin		√
Malaise, fatigue, loss of appetite or « flu-like » symptoms		√
Headaches, stiff neck, fever, nausea, vomiting (signs of aseptic meningitis)		√
Mental confusion, depression		√
Dizziness, lightheadedness		√
Hearing problems		√
Right upper abdominal discomfort or pain		√
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		

This is NOT a complete list of side effects. If you develop any other symptoms while taking VOLTAREN RAPIDE, see your health care provider.

HOW TO STORE IT

Protect tablets from heat (i.e., store at temperatures between 15°C-30°C) and humidity.

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

Keep out of reach of children.

REPORTING SIDE EFFECTS

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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/healthcanada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or
- Call 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

- 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/drugproduct-database.html; the manufacturer's website http://www.Novartis.ca, or by calling 1-800-363-8883.

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VOLTAREN RAPIDE is a registered trademark.

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