PART III CONSUMER INFORMATION

PrVOLTAREN®
PrVOLTAREN® SR
(diclofenac sodium)

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® and PrVOLTAREN® SR were approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will NOT tell you everything about VOLTAREN or VOLTAREN SR. 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 VOLTAREN or VOLTAREN SR for you to relieve pain and swelling in rheumatoid arthritis and osteoarthritis, including degenerative joint disease of the hip.

What it does:

VOLTAREN and VOLTAREN SR (diclofenac sodium), as nonsteroidal anti-inflammatory drugs (NSAIDs), can reduce the chemicals prostaglandins produced by your body which cause pain and swelling.

VOLTAREN and VOLTAREN SR, as nonsteroidal anti-inflammatory drugs (NSAIDs) do NOT cure your illness or prevent it from getting worse. VOLTAREN or VOLTAREN SR 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 or VOLTAREN SR 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**
- **Current pregnancy (after 28 weeks of pregnancy)**
- **Currently breastfeeding (or planning to breastfeed)**
- **Allergy (hypersensitivity) to diclofenac sodium, or ASA (Acetylsalicylic Acid) or other NSAIDs (Nonsteroidal Anti-Inflammatory Drugs), or any of the nonmedicinal ingredients in VOLTAREN or VOLTAREN SR**
- **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**

Do not use VOLTAREN suppositories if you have inflammation of the rectum or anus or have a recent history of bleeding from the rectum or anus.

Patients who took a drug in the same class as VOLTAREN and VOLTAREN SR 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 and VOLTAREN SR 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:

diclofenac sodium.

What the non-medicinal ingredients are:

The enteric coated 50 mg tablets (VOLTAREN) contain black ink, castor oil derivatives, colloidal silicon dioxide, corn starch, hypromellose, iron oxides, lactose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, sodium starch glycolate, talc, titanium dioxide.

The slow-release 75 mg and 100 mg tablets (VOLTAREN SR) contain black ink, carnauba wax, cellulose compounds, cetyl alcohol, colloidal silicon dioxide, hypromellose magnesium stearate, polysorbate 80, povidone, red iron oxide, sucrose, talc, titanium dioxide.

The 50 mg and 100 mg suppositories contain semi-synthetic glycerides.

What dosage forms it comes in:

VOLTAREN 50 mg (enteric-coated) tablet: light brown, round, **VOLTAREN** on one side and **50** on the other.

VOLTAREN 75 mg Slow Release (SR) tablet: light pink, triangular, **VOLTAREN** on one side and **SR 75** on the other.

VOLTAREN 100 mg Slow Release (SR) tablet: pink, round, **VOLTAREN SR** on one side and **100** on the other.

VOLTAREN 50 mg and 100 mg Suppositories:
Bullet shaped, white to yellowish-white colour, with a smooth surface with a fat like odour.

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

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 or VOLTAREN SR:
- **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 and VOLTAREN SR 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 and VOLTAREN SR can result in increased blood pressure and /or worsening of congestive heart failure.

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

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 and VOLTAREN SR 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
- 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

Also, before taking this medication, tell your health care provider if you are pregnant or 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 VOLTAREN or VOLTAREN SR is not recommended in women trying to get pregnant. In women who have difficulty conceiving, stopping VOLTAREN or VOLTAREN SR 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 or VOLTAREN SR.
- Your doctor will monitor your kidney function, your liver function and your blood count to decide if VOLTAREN or VOLTAREN SR needs

to be discontinued or if the dose needs to be changed.

If, at any time while taking VOLTAREN or VOLTAREN SR 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 or VOLTAREN SR might increase the risk of heart attacks or strokes.

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

INTERACTIONS WITH THIS MEDICATION

What About Taking Other Drugs At The Same Time?

See 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 (medicine 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 or VOLTAREN SR. 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 or VOLTAREN SR and ASA than if you took VOLTAREN or VOLTAREN SR alone.

PROPER USE OF THIS MEDICATION

VOLTAREN and VOLTAREN SR is used for maintenance therapy only.

Usual Dose for patients 16 years of age and older:

Medical Condition	Maintenance Dose	Maximum Dose (per day)
VOLTAREN 50 mg enteric-coated tablets		
Rheumatoid Arthritis	50 mg twice daily	100 mg
Osteoarthritis	50 mg twice daily	100 mg
VOLTAREN SR 75 & 100 mg slow-release tablets		
Rheumatoid Arthritis	75 mg once daily	100 mg
Osteoarthritis	75 mg once daily	100 mg
VOLTAREN 50 mg and 100 mg suppositories		
Rheumatoid Arthritis	50 mg once daily	100 mg
Osteoarthritis	50 mg once daily	100 mg

Take VOLTAREN or VOLTAREN SR 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 VOLTAREN or VOLTAREN SR 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 will be using VOLTAREN or VOLTAREN SR for more than 7 days, see your health care provider regularly to discuss whether this medicine is working for you and if it is causing you any unwanted effects.

Swallow the tablet whole with water, do not chew or divide the tablet. It is best to take your dose at the same time each day.

To help reduce the possibility of stomach upset you should take VOLTAREN or VOLTAREN SR tablets immediately after a meal or with food or milk. Also, 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. If stomach upset (indigestion, nausea, vomiting, stomach pain or diarrhea) occurs and continues, contact your doctor.

Using Suppositories
VOLTAREN suppositories (50 and 100 mg) are wrapped in a plastic film. Make sure that the plastic wrapping is fully removed before inserting the suppository into the rectum. It is best to take the suppositories after emptying your bowels.

Do not take suppositories by mouth.

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.

Missed dose:

If you forget to take your scheduled dose, you should not double the next scheduled dose to make up for the missed dose.

Overdose:

If you have accidentally taken more than the prescribed dose of VOLTAREN tablets, suppositories or VOLTAREN SR tablets, **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 or VOLTAREN SR 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 or VOLTAREN SR 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 or VOLTAREN SR, do NOT drive or operate machinery.

VOLTAREN or VOLTAREN SR 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 or VOLTAREN SR and get emergency medical attention IMMEDIATELY**	**STOP taking VOLTAREN or VOLTAREN SR and talk to your physician or pharmacist**
Bloody or black tarry stools, vomiting blood	√	
Spontaneous bleeding or bruising (signs of thrombocytopenia)	√	
Shortness of breath, wheezing, any	√	

SERIOUS SIDE EFFECTS AND WHAT TO DO ABOUT THEM		
Symptom	**STOP taking VOLTAREN or VOLTAREN SR and get emergency medical attention IMMEDIATELY**	**STOP taking VOLTAREN or VOLTAREN SR and talk to your physician or pharmacist**
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		√

SERIOUS SIDE EFFECTS AND WHAT TO DO ABOUT THEM		
Symptom	**STOP taking VOLTAREN or VOLTAREN SR and get emergency medical attention IMMEDIATELY**	**STOP taking VOLTAREN or VOLTAREN SR and talk to your physician or pharmacist**
(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		√
Rectal itching or bleeding		√
Right upper abdominal discomfort or pain		√

This is NOT a complete list of side effects. If you develop any other symptoms while taking VOLTAREN and/or VOLTAREN SR, 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.

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

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

Keep this and all medication out of the reach of children.

REPORTING SUSPECTED SIDE EFFECTS

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
- 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, ON 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.

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: http://www.Novartis.ca

or by contacting the sponsor, Novartis Pharmaceuticals Canada Inc., at:
1-800-363-8883

If you have any additional question about your individual condition, you should contact your health care professional.

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