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 Sandoz-Diclofenac and Sandoz-Diclofenac 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 Sandoz-Diclofenac or Sandoz-Diclofenac SR. Contact your doctor or pharmacist if you have any questions about the drug.

PART III: CONSUMER INFORMATION

Sandoz®-Diclofenac
Sandoz®-Diclofenac SR
(diclofenac sodium)

What the medication is used for:

Your healthcare provider has prescribed Sandoz-Diclofenac or Sandoz-Diclofenac SR for you to relieve pain and swelling in rheumatoid arthritis and osteoarthritis, including degenerative joint disease of the hip. Sandoz-Diclofenac and Sandoz-Diclofenac SR are used for maintenance therapy only.

What it does:

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

Sandoz-Diclofenac SR and Sandoz-Diclofenac SR, as nonsteroidal anti-inflammatory drugs (NSAIDs) do NOT cure your illness or prevent it from getting worse. Sandoz-Diclofenac or Sandoz-Diclofenac 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 SANDOZ-DICLOFENAC OR SANDOZ-DICLOFENAC 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 breast-feeding (or planning to breast-feed)
- allergy (hypersensitivity) to diclofenac sodium, or ASA (acetylsalicylic acid) or other NSAIDs (Nonsteroidal Anti-Inflammatory Drugs), or any of the nonmedicinal ingredients in Sandoz-Diclofenac or Sandoz-Diclofenac SR
- ulcer (active)
- bleeding from the stomach or gut (active)
- inflammatory bowel disease (Crohn’s Disease or Ulcerative Colitis)
- liver disease (active or severe)
- severe or worsening kidney problem or high potassium in the blood

Do not use Sandoz-Diclofenac suppositories if you have an allergy to the ingredients or an allergy to one of the other.

Patients who took a drug in the same class as diclofenac sodium after a type of heart surgery (coronary artery bypass grafting (CABG)) were more likely to have heart attacks, strokes, blood clots in the legs or lungs, and infections or other complications than those who did not take that drug.

Sandoz-Diclofenac and Sandoz-Diclofenac 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 nonmedicinal ingredients are:

The enteric-coated 25 mg and 50 mg tablets (Sandoz-Diclofenac) 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 (Sandoz-Diclofenac) contain black ink, candle 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 semisynthetic glycerides.

What dosage forms it comes in:

Sandoz-Diclofenac: 25 mg (enteric-coated) tablet: yellow, round, slightly biconvex, $ on one side and SR 25 on the other.

Sandoz-Diclofenac: 50 mg (enteric-coated) tablet: light brown, round, slightly biconvex, $ on one side and 50 on the other.

Sandoz-Diclofenac SR 75 mg (slow-release) tablet: light pink, triangular, $ on one side and SR 75 on the other.

Sandoz-Diclofenac SR 100 mg (slow-release) tablet: pink, round, $ on one side and SR 100 on the other.

Sandoz-Diclofenac SR 50 mg and 100 mg suppositories: bullet-shaped, white to yellowish-white colour, with a smooth surface and 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 medical conditions, see your healthcare provider to discuss treatment options other than Sandoz-Diclofenac or Sandoz-Diclofenac SR:

- 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 healthcare provider if you have any of the following:

- high blood pressure
- high cholesterol
- diabetes mellitus or on a low-sugar diet
- gout

- 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
- family history of allergy to NSAIDs; such as acetylsalicylic acid (ASA), celecoxib, diclofenac, diflunisal, ethodolac, fenoprofen, flurbiprofen, ibuprofen, indomethacin, ketoprofen, ketorolac, mefenamic acid, meclofenamic acid, nabumetone, naproxen, oxaprozin, piroxicam, rofecoxib, sulindac, tenoxicam, tiaprofenic acid, tolmetin, or valdecoxib (NOT a complete list)
- family history of asthma, nasal polyposis, long-term swelling of the sinus (chronic sinusitis) or hives

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

While taking this medication:

- tell any other doctor, dentist, pharmacist or other healthcare 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 Sandoz-Diclofenac or Sandoz-Diclofenac SR is not recommended in women trying to get pregnant. In women who have difficulty conceiving, stopping Sandoz-Diclofenac or Sandoz-Diclofenac SR should be considered.

INTERACTIONS WITH THIS MEDICATION

See your healthcare provider or 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
- aspirin
- echinacea
- ephedrine
- ephedrine derivatives
- etodolac, fenoprofen, flurbiprofen, ibuprofen, indomethacin, ketorolac, naproxen, or ibuprofen
- antidepressants
- angiotensin-converting enzyme (ACE) inhibitors
- angiotensin II receptor blockers
- furosemide, hydrochlorothiazide
- lithium
- mefloquine or quinine
- methotrexate or other medications used to treat or prevent cancer
- oral corticosteroids
- probenecid
- quinolone antibacterials

Your healthcare 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 Sandoz-Diclofenac or Sandoz-Diclofenac SR. Take only the amount of ASA prescribed by your healthcare provider. You are more likely to upset or damage your stomach if you take both Sandoz-Diclofenac or Sandoz-Diclofenac SR and ASA than if you took Sandoz-Diclofenac or Sandoz-Diclofenac SR alone.

PROPER USE OF THIS MEDICATION

Usual dose:

<table>
<thead>
<tr>
<th>Medical Condition (Age Group)</th>
<th>Maintenance Dose</th>
<th>Maximum Dose (per day)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sandoz-Diclofenac 25 mg and 50 mg enteric-coated tablets</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rheumatoid Arthritis (16 years of age and older)</td>
<td>Maintenance dose only: 50 mg 2 times a day</td>
<td>100 mg</td>
</tr>
<tr>
<td>Osteoarthritis (16 years of age and older)</td>
<td>Maintenance dose only: 50 mg 2 times a day</td>
<td>100 mg</td>
</tr>
<tr>
<td>Sandoz-Diclofenac SR 75 mg and 100 mg slow-release tablets</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rheumatoid Arthritis (16 years of age and older)</td>
<td>75 mg once daily</td>
<td>100 mg</td>
</tr>
<tr>
<td>Osteoarthritis (16 years of age and older)</td>
<td>75 mg once daily</td>
<td>100 mg</td>
</tr>
<tr>
<td>Sandoz-Diclofenac SR 50 mg and 100 mg enteric-coated tablets suppositories</td>
<td></td>
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</tr>
<tr>
<td>Rheumatoid Arthritis (16 years of age and older)</td>
<td>50 mg</td>
<td>100 mg</td>
</tr>
<tr>
<td>Osteoarthritis (16 years of age and older)</td>
<td>50 mg</td>
<td>100 mg</td>
</tr>
</tbody>
</table>

If your symptoms are not adequately controlled, you should contact your doctor, who may increase the total daily dose to a maximum of 150 mg in divided doses for a short period and with close monitoring. If you are older than 65 years, have liver problems, kidney problems, or heart failure, the maximum total dose per day should not exceed 100 mg of Sandoz-Diclofenac.
Take Sandoz-Diclofenac or Sandoz-Diclofenac SR only as directed by your healthcare 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 healthcare provider recommended. If possible, you should take the lowest dose of this medication for the shortest time period. Taking too much Sandoz-Diclofenac or Sandoz-Diclofenac SR may increase your chances of unwanted and sometimes dangerous side effects, especially if you are elderly, have other diseases or take other medications.

Whether you have been prescribed oral tablets and/or rectal suppositories make sure that you do not take more than a total of 100 mg per day, unless directed by your doctor.

If you will be using Sandoz-Diclofenac or Sandoz-Diclofenac SR for more than 7 days, see your healthcare provider regularly to discuss whether this medicine is working for you and if it is causing you any unwanted effects.

**Sandoz-Diclofenac (enteric-coated tablets):**
Sandoz-Diclofenac tablets are an extended-release product. Tablets should be swallowed whole with water and must not be divided or chewed.

**Taking Sandoz-Diclofenac SR Tablets Once A Day**
If you are taking Sandoz-Diclofenac SR 100 mg tablet or Sandoz-Diclofenac SR 75 mg tablet once a day, it is best to take this tablet at the same time each day unless your doctor has told you differently.

**Taking Sandoz-Diclofenac SR Tablets Twice A Day**
If your doctor has prescribed 150 mg of Sandoz-Diclofenac SR for a short period of time, you should take Sandoz-Diclofenac SR 75 mg tablet twice a day, in the morning and evening.

To help reduce the possibility of stomach upset you should take Sandoz-Diclofenac or Sandoz-Diclofenac 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**
Sandoz-Diclofenac 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.

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

**Missed dose:**
If you forget to take one or more doses of Sandoz-Diclofenac (diclofenac sodium) 25 mg or 50 mg tablets, 50 mg or 100 mg suppositories or Sandoz-Diclofenac SR (diclofenac sodium) 75 and 100 mg tablets, you should not increase the dose of Sandoz-Diclofenac (diclofenac sodium) or Sandoz-Diclofenac SR to make up for the missed dose or doses, but you should continue taking your tablet or suppository at the next prescribed or regular time.

**Overdose:**
If you have accidentally taken more than the prescribed dose of Sandoz-Diclofenac tablets, suppositories or Sandoz-Diclofenac SR tablets, contact your doctor, pharmacist or poison control center immediately, or go to the hospital emergency unit at once. You may require medical attention.

### SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Sandoz-Diclofenac or Sandoz-Diclofenac 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 healthcare provider.

**Diclofenac sodium 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 lightheaded after taking Sandoz-Diclofenac or Sandoz-Diclofenac SR, do NOT drive or operate machinery.**

**Diclofenac sodium may cause you to become more sensitive to sunlight. Any exposure to sunlight or sunlamps may cause sunburn, skin blisters, skin rash, skin redness, itching or discoloration, or vision changes. If you have a reaction from the sun, check with your healthcare provider.**

**Check with your healthcare 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

<table>
<thead>
<tr>
<th>Symptom</th>
<th>STOP taking Sandoz-Diclofenac or Sandoz-Diclofenac SR and get emergency medical attention IMMEDIATELY</th>
<th>STOP taking Sandoz-Diclofenac or Sandoz-Diclofenac SR and talk to your physician or pharmacist</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bloody or black tarry stools</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Shortness of breath, wheezing, any trouble breathing or chest tightness</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Skin rash, lumps, swelling or itching</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Blurred vision, or any visual disturbance</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Any change in the amount or colour of your urine (red or brown)</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Any pain or difficulty experienced while urinating</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Swelling of the feet, lower legs, weight gain</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Vomiting or persistent indigestion, nausea, stomach pain or diarrhea</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Yellow discoloration of the skin or eyes (signs of liver failure), with or without itchy skin</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Malaise, fatigue, loss of appetite</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Headaches, stiff neck</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Mental confusion, depression</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Dizziness, lightheadedness</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Hearing problems</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Rectal itching or bleeding</td>
<td>✔</td>
<td>✔</td>
</tr>
</tbody>
</table>

This is NOT a complete list of side effects. If you develop any other symptoms while taking Sandoz-Diclofenac and/or Sandoz-Diclofenac SR, see your healthcare provider.

### HOW TO STORE IT

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

Protect suppositories from heat (i.e. store at temperatures between 15 and 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 reach of children.**

### 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 0701C

**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.sandoz.ca](http://www.sandoz.ca)
- or by contacting the sponsor, Sandoz Canada Inc., at 1-800-361-3062
- or by written request at:
  - 145, Jules-Léger, Boucherville (QC) Canada J4B 7K8
- or by e-mail at: medinfo@sandoz.com

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