

PART III: CONSUMER INFORMATION**Pr Sandoz Diclofenac Ophtha
(Diclofenac Sodium Ophthalmic Solution)**

0.1% w/v

This leaflet is part III of a three-part "Product Monograph" published when Sandoz Diclofenac Ophtha* was 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 Ophtha. Contact your doctor or pharmacist if you have any questions about the drug.

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

Your doctor has prescribed Sandoz Diclofenac Ophtha (Diclofenac Sodium ophthalmic solution), 0.1% w/v for you which is a nonsteroidal anti-inflammatory drug (NSAID), used to treat eye inflammation after cataract surgery and eye inflammation after a non-penetrating eye injury.

What it does:

Sandoz Diclofenac Ophtha eye drops reduce pain and inflammation by reducing the production of certain substances called prostaglandins.

When it should not be used:

DO NOT USE Sandoz Diclofenac Ophtha if you are allergic to diclofenac sodium, any other ingredient in the formulation (see **What the nonmedicinal ingredients are**), or other medications of the NSAID group, such as acetylsalicylic acid, diflunisal, ibuprofen, flurbiprofen, ketoprofen, indomethacin, mefenamic acid, piroxicam, sulindac, or tiaprofenic acid.

Sandoz Diclofenac Ophtha is not for use in children under 18 years of age.

What the medicinal ingredient is:

Diclofenac sodium, 0.1% w/v

What the nonmedicinal ingredients are:

Boric acid,
Edetate Disodium,
Cremophor EL,
Tromethamine (TRIS),
Sorbic Acid,
Water

What dosage forms it comes in:

Sandoz Diclofenac Ophtha is available in:
Preserved multi-dose bottles of 5mL and twin pack containing 2 bottles of 5 mL per box.

BEFORE taking Sandoz Diclofenac Ophtha , tell your doctor or pharmacist if you:

- are pregnant or are planning to become pregnant while taking this medication;
- are breastfeeding or planning to breastfeed;
- are taking a topical corticosteroid. Taking Sandoz Diclofenac Ophtha and a corticosteroid at the same time may slow wound healing;
- have (had) complicated eye surgery, pre-existing corneal problems, diabetes, problems with your eye surface (such as dry eye), rheumatoid arthritis or multiple eye surgeries. You may be a higher risk for developing serious eye side effects. Taking Sandoz Diclofenac Ophtha more than 24 hours before eye surgery or for more than 14 days after surgery may also increase your risk for developing serious eye side effects;
- have any other medical problem(s);
- wear soft contact lenses. DO NOT administer Sandoz Diclofenac Ophtha while wearing soft contact lenses. Remove lenses before application and reinsert no earlier than 15 minutes after use.

WHILE taking Sandoz Diclofenac Ophtha:

- check with your doctor if you are not getting any relief or if any problems develop, such as an eye infection or bleeding problems;
- report any reactions to your doctor. This is very important because it will help in the early detection and prevention of problems;
- If you experience any vision problems, in particular blurring of vision, DO NOT drive or operate any machinery.

STOP using Sandoz Diclofenac Ophtha and talk to your doctor if you experience any serious problems with your eye(s).

Your regular medical check-ups, including monitoring of eye pressure, are essential.

INTERACTIONS WITH THIS MEDICATION

BEFORE taking Sandoz Diclofenac Ophtha, tell your doctor or pharmacist if you are taking any other drug (either prescription or non-prescription) such as:

- corticosteroids
- medications that prolong bleeding time
- antibiotics

WARNINGS AND PRECAUTIONS**PROPER USE OF THIS MEDICATION**

Sandoz Diclofenac Ophtha is for topical use only.

Usual adult dose:

Cataract surgery

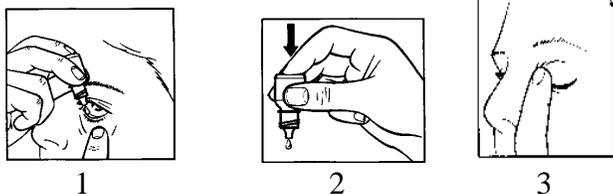
Before surgery: Apply 1 drop into the affected eye(s) up to 5 times during the 3 hours before your scheduled surgery.

After surgery: Apply 1 drop into the affected eye(s) 15, 30 and 45 minutes following surgery. Then apply 1 drop 3 to 5 times per day for up to 4 weeks.

Inflammation from non-penetrating wounds

Apply 1 drop into the affected eye(s) 4 to 5 times per day as directed by your physician.

How to use:



- Wash your hands and sit or stand comfortably. If you wear contact lenses, remove them before using your eye drops.
- Visually inspect the dropper tip to make sure that it is not chipped or cracked.
- Avoid touching the dropper tip against your eye or anything else to avoid contamination. Eye drops and eye dropper must be kept clean.
- Pull down your lower eyelid with a clean finger until there is a 'pocket' between the eyelid and your eye. The drop will go in here (picture 1).
- Bring the bottle tip close to the eye. Do this in front of a mirror if it helps.
- Gently press on the base of the bottle to release one drop of Sandoz Diclofenac Ophtha at a time.
- DO NOT squeeze the bottle: it is designed so that a gentle press on the bottom is all that it needs (picture 2).
- Close your eyelid and gently press the inner corner of your eye with your forefinger for 2 minutes (picture 3).
- If you use drops in both eyes, repeat the steps for your other eye.
- Close the bottle cap firmly immediately after use. DO NOT wipe or rinse the dropper tip.
- If a drop misses your eye, try again.
- Wipe any excess liquid from your face with a tissue.
- If you are to use more than one drop in the same eye, wait at least 5 minutes before applying the next drop. Eye ointments should be applied last.
- Wash your hands to remove any medication.

Overdose:

Overdosage will not usually cause sudden problems. If Sandoz Diclofenac Ophtha is accidentally ingested, fluids should be taken to dilute the medication.

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.

Missed dose:

If a dose of this medication has been missed, it should be taken as soon as possible. However, if it is almost time for the next dose, skip the missed dose and go back to the regular dosing schedule. DO NOT double doses.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Occasionally you may experience a mild to moderate burning sensation when Sandoz Diclofenac Ophtha is instilled in the eye. This symptom usually disappears rapidly, but if it or any other side effects persist, check with your doctor.

Less frequently observed eye side effects are allergic reaction, itchy eye(s), reddening of eye and blurred vision immediately after instillation of the eye drops, eye pain, eye surface inflammation with surface damage, sensitivity to light, abnormal vision, eye allergy, eye swelling, clouding of the eye surface, eyelid swelling, eye irritation, eye discharge, eyelid reddening, swelling or rash, eyelid crusting, eye discomfort, slower healing and a stainable cornea.

Uncommon side effects in the rest of the body are bad taste, feeling of pressure, abdominal pain, feeling weak, chills, dizziness, swelling of the face, fever, headache, problems sleeping, nausea, pain, nose irritation, a viral infection, hives, rash, eczema, skin redness, cough, allergic reaction and vomiting.

If you are using Sandoz Diclofenac Ophtha after cataract surgery, you may feel increased eye pressure (intraocular pressure).

If you are using Sandoz Diclofenac Ophtha after refractive surgery, you may notice tearing.

If you use corticosteroids, have infections or have rheumatoid arthritis, you may develop ulcers, thinning or inflammation of your cornea, which may cause loss of vision.

Report any reactions to your doctor. This is very important because it will help in the early detection and prevention of problems.

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

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Uncommon	Ulcer, thinning or swelling of your cornea		√	
	Outer layer defects of your cornea		√	
	Shortness of breath			√
	Increase in signs and symptoms of asthma		√	
	Severe allergic reaction			√
Unknown	Tiny tears (perforations) in your cornea		√	

This is not a complete list of side effects. For any unexpected effects while taking Sandoz Diclofenac Ophtha contact your doctor or pharmacist.

HOW TO STORE IT

Store at 20°C to 25°C with excursions permitted to 15°C to 30°C. Protect from light.

Keep bottle tightly closed when not in use. Keep this and all medication in a safe place out of the reach and sight of children.

REPORTING SIDE EFFECTS

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- Online at [MedEffect](#);
 - By calling 1-866-234-2345 (toll-free);
 - By completing a Consumer Side Effect Reporting Form and sending it by:
 - Fax to 1-866-678-6789 (toll-free), or
 - Mail to: Canada Vigilance Program
Health Canada, Postal Locator
0701E
Ottawa, ON
K1A 0K9
- Postage paid labels and the Consumer Side Effect Reporting Form are available at [MedEffect](#).

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 on the Health Canada website or by contacting the sponsor,

1-800-361-3062

Or by written request at:
145 Jules-Léger
Boucherville QC
J4B 7K8

Or by e-mail at:
medinfo@sandoz.com

This leaflet was prepared by Sandoz Canada Inc.
Last revised: December 16, 2016