

**CONSUMER INFORMATION**

Pr **VOLTAREN OPHTHA\***  
(Diclofenac Sodium)

**0.1% w/v Ophthalmic Solution**

This leaflet is part III of a three-part "Product Monograph" published when VOLTAREN 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 VOLTAREN 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 VOLTAREN OPHTHA\* for you which is a nonsteroidal anti-inflammatory drug (NSAID), used to treat eye inflammation after cataract surgery and eye inflammation after non-penetrating eye injury.

**What it does:**

VOLTAREN OPHTHA\* eye drops reduce pain and inflammation by reducing the production of certain substances called prostaglandins.

**When it should not be used:**

- are allergic to diclofenac sodium or other medications of the NSAID group such as acetylsalicylic acid, diflusal, ibuprofen, flurbiprofen, ketoprofen, fenoprofen, indomethacin, mefenamic acid, piroxicam, sulindac, tiaprofenic acid or tolmetin;

**What the medicinal ingredient is:**

Diclofenac sodium

**What the nonmedicinal ingredients are:**

*Preserved multi-dose bottles (2.5 mL, 5 mL and 10 mL)*

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

***Unpreserved single dose units (0.3 mL)***

Cremophor EL,  
Boric acid,

Tromethamine (TRIS)  
Water

**What dosage forms it comes in:**

0.1% (diclofenac sodium) w/v ophthalmic solution is available in:  
Preserved multi-dose bottles of 2.5 mL, 5mL and 10 mL  
Unpreserved single-dose units of 0.3 mL

**WARNINGS AND PRECAUTIONS**

**BEFORE taking VOLTAREN OPHTHA\*, tell your doctor or pharmacist if you:**

- are pregnant or intend to become pregnant while taking this medication;
- are breast feeding;
- have any other medical problem(s).

**WHILE taking VOLTAREN OPHTHA\*:**

- check with your doctor if you are not getting any relief or if any problems develop;
- report any untoward reactions to your doctor. This is very important, as it will aid in the early detection and prevention of potential complications.
- If you experience any blurring of vision, do not drive or operate any machinery.

Not for use in children under 18 years of age

Your regular medical checkups are essential

**INTERACTIONS WITH THIS MEDICATION**

**BEFORE taking VOLTAREN OPHTHA\*, tell your doctor or pharmacist if you:**

- are taking any other drug (either prescription or non-prescription);

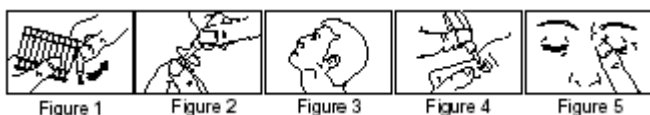
**PROPER USE OF THIS MEDICATION****Usual dose :**

In order to receive the optimum benefits from VOLTAREN OPHTHA\*, it is essential to use the eye drops regularly (usually 3 to 5 times a day) as directed by your physician.

If you are recovering from cataract surgery, instill 1 drop in the conjunctival sac 3 times daily.

**How to use your single dose unit:**

- Cut pouch along dotted line and remove the strip of single use units. Tear off one single dose unit from the strip (Figure 1).
- Hold it by the tab with the nozzle pointing downwards and tap the unit gently until all the air bubbles are above the solution.
- Twist the tab off the single dose unit (Figure 2). Make sure that the tip of the unit does not touch anything.
- Hold the single dose unit in one hand between the thumb and forefinger. With your head tilted back (Figure 3), use the forefinger of your other hand to pull down the lower lid of your eye.
- Place the single dose unit tip close to your eye, but without touching your eye or lid, and gently squeeze the unit to allow one drop to be applied (Figure 4).
- Close your eyelid and gently press the inner corner of your eye with your forefinger for one minute (Figure 5).
- Discard the single dose unit and the remaining solution.



**Overdose:**

Overdosage will not ordinarily cause acute problems. If VOLTAREN 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 VOLTAREN 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 side effects are allergic reaction, itching, reddening of eye and blurred vision immediately after installation of the eye drops, eye pain, sensitivity to light, bad taste, feeling of pressure, and a stainable cornea.

If you experience blurring of vision, do not drive or operate any machinery.

Corneal epithelial defects have been observed.

In patients with risk factors of corneal ulcer and thinning such as during the use of corticosteroids or with concomitant diseases such as infections or rheumatoid arthritis, topical NSAIDS (including diclofenac) have been associated, in rare cases with corneal ulcer or thinning which might become sight-threatening. In rare cases shortness of breath, and increase in signs and symptoms of asthma have been reported.

Report any untoward reactions to your doctor. This is very important, as it will aid in the early detection and prevention of potential complications.

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	
Common				
Uncommon	Corneal Ulcer or thinning		√	
	Cornea outer layer defects		√	
	Shortness of breath		√	
	Increase in signs and symptoms of asthma		√	

*This is not a complete list of side effects. For any unexpected effects while taking VOLTAREN OPHTHA\*, contact your doctor or pharmacist.*

**HOW TO STORE IT**

Store preserved multi-dose bottles at room temperature (15° to 30° C) and protect from light. Store single dose units in a cool place up to 25°C.

Keep bottle tightly closed when not in use. Keep this and all medication in a safe place out of the 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 0701D  
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 by contacting the sponsor,

Novartis Pharmaceuticals Canada Inc.,  
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H9S 1A9

1-800-363-8883

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