

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr VOLTAREN® OPHTHA

Diclofenac Sodium Ophthalmic Solution 0.1% w/v

Read this carefully before you start taking VOLTAREN® OPHTHA and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about VOLTAREN OPHTHA.

What is VOLTAREN OPHTHA used for?

VOLTAREN OPHTHA is used to treat:

- eye inflammation after cataract surgery and
- eye inflammation after a non-penetrating eye injury.

How does VOLTAREN OPHTHA work?

VOLTAREN OPHTHA is a nonsteroidal anti-inflammatory drug (NSAID). It helps reduce chemicals produced in your eye (prostaglandins) which cause pain and swelling.

What are the ingredients in VOLTAREN OPHTHA?

Medicinal ingredients: Diclofenac sodium

Non-medicinal ingredients: Boric acid, Edetate Disodium, Polyoxyl 35 castor oil, Purified Water, Sorbic Acid, Tromethamine (TRIS).

VOLTAREN OPHTHA comes in the following dosage forms:

Ophthalmic Solution, 0.1% w/v

VOLTAREN OPHTHA is available in preserved multi-dose bottles of 5mL.

Do not use VOLTAREN OPHTHA if:

- you are allergic to diclofenac sodium, any other ingredient in the formulation (see What are the ingredients- nonmedicinal ingredients)
- you have had reactions to other NSAID medications, such as:
 - acetylsalicylic acid
 - diflunisal
 - ibuprofen
 - flurbiprofen

- ketoprofen
- indomethacin
- mefenamic acid
- piroxicam
- sulindac
- tiaprofenic acid.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take VOLTAREN OPHTHA. Talk about any health conditions or problems you may have, including if you:

- Have had complicated eye surgery or multiple eye surgeries
- Have pre-existing corneal problems or problems with your eye surface (such as dry eye)
- Have diabetes
- Have rheumatoid arthritis

Other warnings you should know about:

- Taking VOLTAREN OPHTHA more than 24 hours before eye surgery or for more than 14 days after surgery may increase your risk for developing serious eye side effects;
- Check with your healthcare professional 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 healthcare professional. 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.
 - Your regular medical check-ups, including monitoring of eye pressure, are essential.

Pregnancy and breast feeding

You should tell your healthcare professional if you are pregnant or think that you may be pregnant. You should not use VOLTAREN OPHTHA while pregnant unless absolutely necessary.

As with other anti-inflammatory medicines, you must not use VOLTAREN OPHTHA during the last 3 months of pregnancy, as it could harm your unborn child or cause problems at delivery.

You should tell your healthcare professional if you are breast-feeding.

You should not breast-feed if you are taking VOLTAREN OPHTHA as it might be harmful for your infant.

Your healthcare professional will discuss with you the potential risk of using VOLTAREN OPHTHA during pregnancy or breast-feeding.

Fertility in Women:

VOLTAREN OPHTHA is not recommended to use in women attempting to conceive as it may impair female fertility.

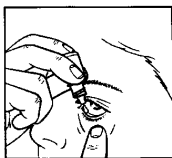
Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with VOLTAREN OPHTHA:

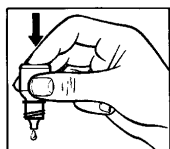
- Corticosteroids
- Medications that prolong bleeding time

How to take VOLTAREN OPHTHA:

VOLTAREN OPHTHA is for topical use only.



1



2



3

- 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 VOLTAREN 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.

Usual 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 healthcare professional.

Overdose:

If VOLTAREN OPHTHA is accidentally ingested, fluids should be taken to dilute the medication.

If you think you, or a person you are caring for, have taken too much Voltaren Ophtha, contact a healthcare professional, 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.

What are possible side effects from using VOLTAREN OPHTHA?

These are not all the possible side effects you may have when taking VOLTAREN OPHTHA. If you experience any side effects not listed here, tell your healthcare professional.

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 healthcare professional.

Uncommon eye side effects are: 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, pink eye, 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 and vomiting.

If you are using VOLTAREN OPHTHA after cataract surgery, you may feel increased eye pressure (intraocular pressure).

If you are using VOLTAREN 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 healthcare professional. This is very important because it will help in the early detection and prevention of problems.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
UNCOMMON			
Ulcer (sore on your eye)		✓	
Swelling (keratitis) or other issues with your cornea (the front of your eye): Difficulty opening your eye due to pain, irritation or light sensitivity; feeling like something is in your eye; blurry / decreased vision		✓	
Shortness of breath			✓
Increase in signs and symptoms of asthma		✓	
Allergic Reaction: difficulty swallowing or breathing, wheezing, feeling sick to your stomach and throwing up, hives or rash, swelling of the face, lips, tongue or throat.			✓
UNKNOWN			
Tiny tears (perforations) in your cornea		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

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

Storage:

Store at 20°C to 25°C. Protect from light.

Keep bottle tightly closed when not in use. Keep this and all medication in a safe place.

Keep out of the reach and sight of children.

If you want more information about VOLTAREN OPTHHA:

- 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/medeffect-canada/adverse-reaction-reporting.html>; the manufacturer's website www.novartis.ca, or by calling 1-800-363-8883.

This leaflet was prepared by Novartis Pharmaceuticals Canada Inc.

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