

VOLTAREN OPHTHA™ Eye Drops 0.1%

Diclofenac sodium

CONSUMER MEDICINE INFORMATION

What is in this leaflet

Read this leaflet carefully before you start to use Voltaren Ophtha Eye Drops.

This leaflet answers some common questions about Voltaren Ophtha Eye Drops. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine.

You can also download the most up to date leaflet from www.medsafe.govt.nz.

The updates may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Voltaren

Ophtha against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

What Voltaren Ophtha is used for

Voltaren Ophtha contains diclofenac sodium.

It belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs).

NSAIDs relieve pain and reduce inflammation (i.e. swelling, redness and throbbing).

This medicine is used to treat inflammation of the eye e.g. inflammation which occurs as a result of surgery.

Before prescribing Voltaren Ophtha Eye Drops your doctor will have examined your eye(s) and decided that this is the right medicine for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

It is available only with a doctor's prescription.

Ask your doctor if you have any questions about why Voltaren Ophtha has been prescribed for you.

Use in children

There is not enough information to recommend the use of this medicine for children.

Before you use Voltaren Ophtha

When you must not use it

Do not use Voltaren Ophtha if you have ever had an allergic reaction or attack of asthma after taking or using:

- any medicine containing diclofenac, including Voltaren tablets, Voltaren suppositories, Voltaren Rapid tablets, Voltaren Emulgel or Voltaren Spray. Other brands containing diclofenac are available.
- aspirin or any other NSAID
- any of the ingredients listed under Product description.

Some of the symptoms of an allergic reaction may include:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

If you are not sure if you are taking or using any of the medicines above ask your doctor or pharmacist for advice.

Do not use Voltaren Ophtha if:

- the safety seal around the closure and neck area is broken
- the bottle/packaging shows signs of tampering
- the expiry date on the bottle/carton has passed.

If you use this medicine after the expiry date has passed, it may not work.

Do not put the eye drops into your eye(s) while you are wearing soft contact lenses.

The preservative in Voltaren Ophtha Eye Drops, benzalkonium chloride, may be deposited in soft contact lenses. You can put your soft contact lenses back into your eyes 15 minutes after you have used Voltaren Ophtha Eye Drops.

If you are not sure whether you should start using Voltaren Ophtha talk to your doctor.

Before you start to use it

Tell your doctor if you have allergies to any other medicines or any substances such as foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- an eye infection
- stomach or bowel ulcers or other bowel trouble
- a tendency to bleed
- problems with your cornea
- asthma.

Your doctor can discuss the risks and benefits involved.

Tell your doctor if you are pregnant or intend to become pregnant.

Voltaren Ophtha is not recommended in pregnant women.

Your doctor will discuss the risks and benefits of using Voltaren Ophtha Eye Drops when pregnant.

Tell your doctor if you are breast-feeding or intent to breast-feed.

Voltaren Ophtha is not recommending while breast-feeding.

Your doctor will discuss the risks and benefits of using Voltaren Ophtha Eye Drops when breastfeeding.

If you have not told your doctor about any of the above, tell them before you start to use Voltaren Ophtha Eye Drops.

Using or taking other medicines

Tell your doctor or pharmacist if you are using other eye drops, ointments or taking any other medicines. This includes any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines and Voltaren Ophtha may interfere with each other.

These include:

- medicines used to thin the blood or prevent blood clots such as warfarin, apixaban, dabigatran, or rivaroxaban
- steroid eye drops or eye ointment used to treat inflammation.

These medicines may be affected by Voltaren Ophtha or may affect how well it works. You may need different amounts of your medicines, or you may need to use different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using this medication.

How to use Voltaren Ophtha

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

The dosing instructions will be printed on the label that your pharmacist puts on the bottle or carton.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

How much to us

The usual dose of Voltaren Ophtha is:

Before surgery

Use up to 5 drops during the 3 hours before surgery.

After surgery

Use one (1) drop 3 times on the day of surgery followed by one (1) drop 3 to 5 times daily.

Relief of pain, sensitivity to light, post-traumatic inflammation

One drop 4 to 6 hourly.

When pain is due to surgery use one to two drops in the hour before surgery, then one to two drops within the first 15 minutes after surgery and one drop 4 to 6 hourly for 3 days after surgery.

How to use it

If you wear soft contact lenses, remove your contact lenses before using this medicine. Wait for 15 minutes after using

it before reinserting your contact lenses into your eyes.

Wearing your lenses is discouraged during treatment of inflammation.

One of the ingredients in Voltaren Ophtha is benzalkonium chloride which can affect contact lenses.

Follow these steps to put the drops in your eyes

1. Wash your hands before using the drops.
2. Open the bottle.
3. Make sure the tip of the dropper does not touch anything as this may contaminate the solution.
4. Hold the bottle in one hand between the thumb and forefinger.
5. With your head tilted back, use the forefinger of your other hand to pull down the lower lid of the eye to be treated.
6. Place the dropper close to your eye, but without touching your eye or eyelid, and gently squeeze so that one drop falls into the pouch between your lower eyelid and your eye, and then release your lower eyelid.
7. Close your eye and gently press the inner corner of your eye with your forefinger for one minute.
8. Treat your other eye in the same way if your doctor has told you to do this.
9. Replace the lid on the bottle.
10. Discard the bottle and remaining solution four weeks after opening.

If you are using any other eye drops at the same time as Voltaren Ophtha, leave an interval of at least 5 minutes between each eye drop to stop the drops being washed out of the eye.

How long to use it

Continue using your medicine for as long as your doctor tells you.

If you forget to use it

If you forget to use Voltaren Ophtha you should put the drops that you missed in the eye(s) as soon as you remember, and then go back to using them as recommended by your doctor.

If it is almost time for your next dose, skip the dose you missed and continue using them as recommended.

Do not use a double dose to make up for the dose that you missed.

If you have trouble remembering to use your medicine, ask your pharmacist for some hints.

If you use too much (overdose)

If you accidentally put too many drops in your eye(s) immediately rinse your eye(s) with warm water.

Immediately telephone your doctor, the National Poisons Centre on 0800 POISON or 0800 764 766 or go to Accident and Emergency at the nearest hospital. Do this even if there are no signs of discomfort or poisoning.

While you are using Voltaren Ophtha

Things you must do

Tell your doctor if you have any crusty discharge from your eyes while using Voltaren Ophtha.

This may mean your eyes are infected and you may need additional treatment.

Tell your doctor if your symptoms persist, worsen or recur.

If you become pregnant while using this medicine, tell your doctor immediately.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using Voltaren Ophtha.

Tell any other doctors, dentists and pharmacists who treat you that you are using this medicine.

If you feel that Voltaren Ophtha is not helping your condition, tell your doctor (or pharmacist).

Keep all your doctor's appointments so that your progress can be checked.

Tell your doctor if, for any reason, you have not used Voltaren Ophtha exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Things you must not do

Do not stop using your medicine or lower the dosage without asking your doctor.

Do not use Voltaren Ophtha to treat any other complaints unless your doctor or tells you to.

Do not give this medicine to anyone else, even if they have the same complaint as you.

Do not let children handle Voltaren Ophtha.

Things to be careful of

Be careful driving or operating machinery until you know how Voltaren Ophtha affects you.

This medicine may cause blurred vision in some people. If you get blurred vision when you use it, do not drive, operate machinery or do anything else that could be dangerous until this effect has worn off.

Side effects

Tell your doctor as soon as possible if you do not feel well while using Voltaren Ophtha.

This medicine helps most people in treating pain and inflammation but it may have unwanted effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- pain, itching, redness, discomfort or irritation of your eye
- blurred vision immediately after using the drops
- gritty foreign body sensation in your eye
- unusual sensitivity of your eyes to light.

The above list includes the more common side effects of your medicine. They also occur with many other eye drops and are usually mild and short-lived.

Additional side effects that are noticed less often include:

- allergic conditions such as swollen, runny eyes, itching or rash elsewhere on your body, cough, sneezing, runny or blocked nose, facial pressure or pain
- discharge from the eye
- crusty or irritated eyelids
- eye and eyelid swelling
- eyelid redness or itchiness
- watery eyes
- damage, scarring, thinning or cloudiness of the eye surface
- increase in eye pressure
- impaired wound healing.

Tell your doctor as soon as possible if you notice any of the following:

- changes in your vision other than temporary blurring
- wheezing or difficulty breathing.

The above list includes more serious side effects which may require medical attention. Serious side effects are rare.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is

making you feel unwell while using Voltaren Ophtha.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using Voltaren Ophtha

Storage

Keep your eye drops in a cool dry place where the temperature stays below 25 degrees C. Do not freeze them.

Protect your eye drops from light.

Do not store Voltaren Ophtha or any other medicine in the bathroom or near a sink. Do not put it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep Voltaren Ophtha in a safe place away from the sight or reach of children.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Put the top back on the bottle right away after use to avoid contamination.

Disposal

Write the date on the bottle when you open the eye drops and throw away any remaining amount after 4 week.

If your doctor tells you to stop using Voltaren Ophtha or it has passed its expiry date, ask your pharmacist what to do with any that is left over.

Product description

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What it looks like

Voltaren Ophtha is a slightly,
yellowish sterile eye drop solution.

TM trademark.

Internal reference: v1o091122cNZ
based on v1o091122iNZ

Ingredients

Voltaren Ophtha contains
diclofenac sodium 1 mg in 1 mL as
the active ingredient.

It also contains:

- benzalkonium chloride (as a preservative)
- disodium edetate
- hydroxypropyl gamma
- cyclodextrin
- hydrochloric acid
- propylene glycol
- trometamol
- tyloxapol
- water for injections.

Supplier

Voltaren Ophtha is supplied in New
Zealand by:

Novartis New Zealand Limited

PO Box 99102

Newmarket

Auckland 1149

New Zealand.

Free Phone: 0800 354 335.

Date of preparation

This leaflet was prepared in
November 2022.