

Voltaren™ Ophtha

diclofenac sodium

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you use Voltaren Ophtha Eye Drops.

This leaflet answers some common questions about Voltaren Ophtha. It does not contain all of 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.novartis.com.au

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 expected benefits of you using Voltaren Ophtha against the risks this medicine could have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What Voltaren Ophtha is used for

This medicine is used to treat inflammation of the eye e.g.

inflammation which occurs as a result of surgery.

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).

Ask your doctor if you have any questions about why this medicine has been prescribed 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.

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 sodium, including Voltaren tablets or suppositories
- any similar medicine such as Voltaren Rapid tablets (diclofenac potassium), Voltaren Emulgel (diclofenac diethylammonium), aspirin or any other NSAID, or any other medicine to relieve pain or reduce swelling

- any of the ingredients listed at the end of this leaflet.

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.

Do not use this medicine if the expiry date has passed, the packaging is torn or the safety seal around the closure and neck area is broken.

If it has expired or is damaged, return it to your pharmacist for disposal.

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, foods, preservatives or dyes.

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

- stomach ulcer, severe attacks of indigestion or other stomach or bowel trouble
- known bleeding tendency
- asthma
- an eye infection that is not being treated.

Tell your doctor if:

- **You are pregnant, or intend to become pregnant**

Your doctor will discuss the possible risks and benefits of using Voltaren Ophtha during pregnancy.

Voltaren Ophtha eye drops should not be used in early pregnancy or during the third trimester of pregnancy.

- **You are breast-feeding or intend to breast-feed**

Your doctor will discuss the possible risks and benefits of using Voltaren Ophtha when you are breast-feeding.

If you have not told your doctor about any of the above, tell him/her before you start using Voltaren Ophtha.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your 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
- steroid eye drops or eye ointment used to treat inflammation
- voriconazole, a medication used to treat fungal infections.

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 take different medicines.

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

How to use Voltaren Ophtha

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

They may differ from the information contained in this leaflet.

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

How much to use

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.

How to use it

This medicine is available in a multidose bottle and in single dose units.

If you are using the multidose bottle and 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 multidose bottle (benzalkonium chloride) can affect contact lenses.

Follow these steps if you are using the multidose bottle:

1. Wash your hands before using the drops.
2. Open the multidose 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 middle finger.
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 multidose bottle.
10. Discard the multidose bottle and remaining solution four weeks after opening.

Follow these steps if you are using the single dose units:

1. Wash your hands before using the drops.
2. Open the blister pack of single dose units.
3. Remove the strip of single dose units and tear off one single dose unit from the strip.

Hold it by the tab with the nozzle pointing downwards and tap gently until all the air bubbles are above the solution.
4. Twist the tab off the single dose unit.
5. Make sure the tip of the single dose unit does not touch anything as this may contaminate the solution.
6. Hold the single dose unit in one hand between the thumb and forefinger.
7. With your head tilted back, use the forefinger of your other hand to pull down the lower lid of the eye to be treated.
8. Place the single dose unit tip 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.
9. Close your eye and gently press the inner corner of your eye with your forefinger for one minute.
10. Treat your other eye in the same way if your doctor has told you to do this.

11. Discard each single dose unit immediately after use.

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 it is almost time for your next dose, skip the dose you missed and use your next dose when you are meant to.

Otherwise, use it as soon as you remember, and then go back to using your medicine as you would normally.

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

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

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

If you use too much (overdose)

Immediately telephone your doctor, the Poisons Information Centre on 13 11 26 or go to Accident and Emergency at the nearest hospital if you think that you or anyone else may have accidentally swallowed the contents of the multidose bottle or single dose unit of Voltaren Ophtha. 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.

Things you must not do

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

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

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

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 or pharmacist as soon as possible if you do not feel

well while you are using Voltaren Ophtha.

This medicine helps most people with inflammation of the eye, but it may have unwanted side 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 attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

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 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.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Some of these side effects can only be found when your doctor checks your eyes from time to time to check your progress.

After using Voltaren Ophtha

Storage

Multidose Bottle

Keep your eye drops in a cool dry place where the temperature stays below 25°C.

Protect your eye drops from light and do not freeze them.

Discard any remaining contents four weeks after opening.

Single Dose Units

Keep your eye drops in the refrigerator (2-8°C) until it is time to use them.

Once the inner blister or pouch is open, keep the eye drops in a cool dry place where the temperature stays below 25 degrees C for up to one month.

Do not use the eye drops after more than one month when stored below 25 degrees C.

Discard each single dose unit and any remaining solution in it immediately after use. Do not save unused contents.

Do not store Voltaren Ophtha or any other medicine in the

bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep your eye drops in a safe place away from the sight and reach of children.

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

Disposal

If your doctor tells you to stop using this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product Description

What it looks like

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

It comes in in a multidose bottle or in *strips of 5 single dose units. Each strip of 5 single dose units is sealed in a blister or pouch to protect it from light, air and water.

Each bottle contains 5 mL and each single dose unit contains 0.3 mL.

*A box of single dose units contains 6 x 5 i.e. 30 single dose units.

Ingredients

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

Voltaren Ophtha multidose bottle also contains:

- benzalkonium chloride (as a preservative)
- disodium edetate
- hydroxypropyl gamma
- cyclodextrin
- hydrochloric acid
- propylene glycol
- trometamol

- tyloxapol
- water for injections.

*Voltaren Ophtha single dose units contain:

- PEG-35 castor oil
- boric acid
- trometamol
- water for injections.

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Supplier

These products are supplied in Australia by:

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*Single Unit Dose: AUST R 51527

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*This dosage form is currently not available.

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