

LEAFLET

Voltarol®
Ophtha Multidose
1mg/ml Eye Drops Solution Diclofenac sodium

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Voltarol Ophtha Multidose Eye Drops is and what it is used for
2. What you need to know before you use Voltarol Ophtha Multidose Eye Drops
3. How to use Voltarol Ophtha Multidose Eye Drops
4. Possible side effects
5. How to store Voltarol Ophtha Multidose Eye Drops
6. Contents of the pack and other information

1. What Voltarol Ophtha Multidose Eye Drops is and what it is used for

Voltarol Ophtha Multidose Eye Drops contains the active substance diclofenac sodium. This is one of a group of medicines called non-steroidal anti-inflammatory drugs. These drops are used to help keep the pupil open during eye surgery; to treat inflammation of the eye associated with cataract surgery or after laser surgery for glaucoma; to treat pain and discomfort associated with excimer laser surgery or accidental non-penetrating injury to the eye; to provide relief from the ocular signs and symptoms of Seasonal Allergic Conjunctivitis (hayfever). Doctors sometimes prescribe these eye drops for other purposes. Consult your doctor if this applies to you.

2. What you need to know before you use Voltarol Ophtha Multidose Eye Drops

Do not use Voltarol Ophtha Multidose Eye Drops:

- If you are allergic to diclofenac sodium or any of the other ingredients of this medicine (listed in section 6).
- If you have had an allergic reaction, skin rash, blocked nose or wheezing after taking aspirin or any other medicine used to treat painful conditions of the joints and muscles.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Voltarol Ophtha Multidose Eye drops:

- If you have a blood clotting disorder or are taking anti-coagulants e.g. warfarin.
- If you are pregnant or breast-feeding.
- If you are suffering from any other eye disorder eg. eye infection, or using other medications in the eye e.g. steroids.

Other medicines and Voltarol Ophtha Multidose Eye Drops

Tell your doctor, pharmacist or nurse if you are using, have recently used or might use any other medicines.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Pregnancy

Voltarol Ophtha Multidose Eye Drops should not be used if you are in the last 3 months of pregnancy. You should not use Voltarol Ophtha Multidose Eye Drops during the first 6 months of pregnancy unless clearly necessary and advised by your doctor. If you need treatment during this period, the lowest dose for the shortest time possible should be used.

Oral forms (e.g. tablets) of diclofenac can cause adverse effects in your unborn baby. It is not known

if the same risk applies to Voltarol Ophtha Multidose Eye Drops when it is used in the eye.

Driving and using machines

Do not drive a motor vehicle or operate machinery if your vision becomes blurred immediately after you have inserted the drops. Wait until your vision clears.

Voltarol Ophtha Multidose Eye Drops contains benzalkonium chloride

This medicine contains 0.0014 mg benzalkonium chloride in each drop, which is equivalent to 0.05 mg/ml.

Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. You should remove contact lenses before using this medicine and put them back 15 minutes afterwards.

Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or disorders of the cornea (the clear layer at the front of the eye). If you feel abnormal eye sensation, stinging or pain in the eye after using this medicine, talk to your doctor.

3. How to use Voltarol Ophtha Multidose Eye Drops Dosage

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dosage is:

Adults including the elderly:

Before cataract surgery:

One drop 4 times during the 2 hours before surgery

After cataract surgery:

One drop 4 times daily up to 28 days

After excimer laser:

One drop every 2-5 hours for up to 24 hours

After accidental non-penetrating injury:

One drop 4 times daily for up to 2 days

After laser surgery for glaucoma:

One drop 4 times daily for up to 7 days

Seasonal Allergic Conjunctivitis:

One drop into each eye 4 times daily for as long as directed by your doctor

After corneal surgery:

One drop 4 times daily for up to 2 days

After squint surgery:

One drop 4 times daily in week 1

One drop 3 times daily in week

2 One drop 2 times daily in week

3 As required in week 4

Use in children

Children:

Not indicated.

Your doctor may advise you to use this medicine in a different way, so follow your doctor's directions about when and how to use your medicine, and read the label. Your pharmacist may also help if you are not sure.

How to use your eye drops

If your doctor recommends that you use Voltarol Ophtha Multidose Eye Drops with another eye drop, an interval of at least 5 minutes between the application of the different eye drops must be allowed.

1. Wash your hands.
2. If you wear contact lenses, remove them before using the drops and do not replace for at least 5 minutes if they are hard lenses, 15 minutes if they are soft lenses.
3. Remove cap from the dropper bottle.
4. Hold the bottle in one hand between your thumb and forefinger.

5. Tip your head backwards, while pulling the lower eyelid gently downwards with the other hand. Place the dropper tip close to your eye, but not touching the eye or lid and gently squeeze the bottle to allow one drop to be applied.
6. Close your eyelid and gently press the corner of your eye with your forefinger for one minute. Keep the eye closed for a further two minutes.
7. Repeat for the other eye if necessary.
8. Replace cap and wash your hands.

Note: Do not touch your eye or any other surface with the tip of the dropper.

Follow these instructions carefully, consult your pharmacist if there is anything you do not understand. If you forget to use your eye drops, put them in as soon as possible.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Effects which may occur are:

- Shortness of breath or worsening of asthma
- Allergic reactions such as swelling of the eyelids, rash or hayfever symptoms
- Damage to the cells on the surface of cornea (the membrane covering the front of the eye), corneal thinning or ulcers that might result in loss of sight
- Pain, itching, redness or smarting in your eye
- Gritty, foreign body sensations in your eye
- Itching, inflammation and blurred vision immediately after applying the drop
- Unusual sensitivity to light.
- Mild to moderate eye irritation

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

HPRA Pharmacovigilance

Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.hpra.ie

e-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Voltarol Ophtha Multidose Eye Drops

This medicinal product does not require any special storage.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and bottle after EXP. The expiry date refers to the last day of that month.

Do not use for longer than four weeks after opening.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Voltarol Ophtha Multidose Eye Drops contains

The active substance is diclofenac sodium 0.1% w/v.

The other ingredients are benzalkonium chloride (as a preservative), disodium edetate, hydroxypropyl γ -cyclodextrin, hydrochloric acid, propylene glycol, trometamol, tyloxapol and water for injections.

What Voltarol Ophtha Multidose Eye Drops looks like and contents of the pack

The bottle contains 5 ml of eye drops.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Laboratoires THEA, 12 rue Louis Bleriot, 63017 Clermont-Ferrand Cedex 2, France.

Manufacturer:

EXCELVISION, rue de la Lombardière F-07100 Annonay, France.

This leaflet only applies to Voltarol Ophtha Multidose Eye Drops and not to any other product.

This leaflet was last revised in August 2024.

If you would like any more information, or would like the leaflet in a different format, please contact Medical Information at THEA Pharma Ltd, telephone number +44 (0)345 521 1290.