

OCUDOR DORZOLAMIDE HYDROCHLORIDE EYE DROPS 2% W/V

Dorzolamide Hydrochloride (2% w/v)

What is in this leaflet

1. What Dorzolamide Hydrochloride eye drops is used for
2. How it works
3. Before you use Dorzolamide Hydrochloride eye drops
4. How to use Dorzolamide Hydrochloride eye drops
5. While you are using it
6. Side effects
7. Storage and Disposal of Dorzolamide Hydrochloride eye drops
8. Product Description
9. Manufacturer
10. Product Registration Holder
11. Date of revision

What Dorzolamide Hydrochloride eye drops is used for

The preparation is indicated to treat

1. Ocular hypertension
2. Open-angle glaucoma.

How Dorzolamide Hydrochloride eye drops works

Dorzolamide Hydrochloride eye drops is an ophthalmic carbonic anhydrase inhibitor which reduces high pressure in the eye.

Before you use Dorzolamide Hydrochloride eye drops

- When you must not use it

Do not use Dorzolamide Hydrochloride eye drops if you

- are **allergic** (hypersensitive) to Dorzolamide Hydrochloride eye drops or any of the other ingredients in this solution

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine. Tell your doctor if you are pregnant or planning to become pregnant. Dorzolamide Hydrochloride eye drops

should not be used during pregnancy unless your doctor still recommends it.

Dorzolamide Hydrochloride eye drops Hydrochloride eye drops should not be used while breast-feeding.

- Before you start to use it

Before treatment with Dorzolamide Hydrochloride eye drops, tell your doctor if you

- have or have had **liver** problems in the past
- have been told you have a **corneal defect**
- have had any **allergies** to any medicines
- have had, or are about to have eye **surgery**
- have suffered an **eye injury** or have an **eye infection**
- have a prior history of **kidney stones**
- are taking orally another **carbonic anhydrase inhibitor such as acetazolamide**
- **wear contact lenses**

- Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

In particular you should tell your doctor if you are taking another carbonic anhydrase inhibitor such as acetazolamide. You may be taking this type of medicine by mouth, as eye drops, or by some other method.

How to use Dorzolamide Hydrochloride eye drops

- How much to use

Always use Dorzolamide Hydrochloride eye drops exactly as your doctor has told you. You should

check with your doctor or pharmacist if you are not sure.

The appropriate dosage and duration of treatment will be established by your doctor.

When Dorzolamide Hydrochloride eye drops is used alone, the usual drop is one drop in the affected eye(s) three times a day, for example in the morning, in the afternoon and in the evening.

If your doctor has recommended you use Dorzolamide Hydrochloride eye drops with a beta-blocker eye drop (medicines which lower the pressure of the eye), then the usual drop is one drop of Dorzolamide Hydrochloride eye drops in the affected eye(s) two times a day, for example in the morning and in the evening.

If you use Dorzolamide Hydrochloride eye drops with another eye drop, leave at least 10 minutes between putting in Dorzolamide Hydrochloride eye drops and the other medicine. Alternatively if you are going to use Dorzolamide Hydrochloride eye drops to replace another eye drop medicine, used to lower eye pressure, you should stop using the other medicine after using the proper dosing on one day, and start Dorzolamide Hydrochloride eye drops on the next day.

- When to use it

In the morning and in the evening. You should check with your doctor or pharmacist if you are not sure.

Do not change the dosage of the drug without consulting your doctor. If you must stop treatment, contact your doctor immediately.

- How long to use it

Dorzolamide Hydrochloride eye drops should be used every day to work proper, if you must stop treatment, contact your doctor immediately.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

- If you forget to use it

It is important to use Dorzolamide Hydrochloride eye drops as prescribed by your doctor.

If you miss a dose, apply it as soon as possible. However, if it is almost time for the next dose, skip the missed dose and go back to your regular dosing schedule.

Do not use a double dose to make up for forgotten individual doses.

- If you use too much (overdose)

If you put too many drops in your eye or swallow any of the contents, you should contact your doctor immediately.

While you are using it

- Things you must do

It is recommended that you wash your hands before putting in your eye drops.

It may be easier to apply your drops in front of the mirror.

Insert Cap:

1. Snap off the dust cover by turning it clockwise to break the seal. Pull off the dust cover (Which can be thrown away).
2. Unscrew the inner cap (it should be retained).
3. Tilt head backwards. Dispenses drops with gentle pressure. Do not touch dropper tip to the surface of the eye. Put the inner cap back on the bottle after every use, tighten the cap on the nozzle.

Spike Cap:

1. Tighten the cap on the nozzle.
2. The spike in the cap will pierce the tips of the vial.
3. Dispense drops with gentle pressure. Replace the cap after every use.

- Things you must not do

Do not change the dosage of the drug without consulting your doctor. If you must stop treatment, contact your doctor immediately.

Do not allow the tip of the container to touch your eye or areas around your eye. It may become contaminated with bacteria that can cause eye infection leading to serious damage of the eye, even loss of vision. To avoid possible contamination of the container, keep the tip of the container away from contact with any surface.

- Things to be careful of

- **Stop using** Dorzolamide Hydrochloride eye drops and contact your doctor immediately if you suspect that Dorzolamide Hydrochloride eye drops is causing an allergic reaction for example, skin rash or itching, inflammation of the eye.
- **Driving and using medicines** Dorzolamide Hydrochloride eye drops may cause dizziness and visual disturbances in some patients. Do not drive or use any tools or machines until the symptoms have cleared.

Important information about some of the ingredients of Dorzolamide Hydrochloride eye drops

Dorzolamide Hydrochloride eye drops contain the preservative benzalkonium chloride.

- Benzalkonium chloride may cause eye irritation
- Benzalkonium chloride is known to discolour soft contact lenses
- Avoid contact with soft contact lenses

Remove contact lenses prior to application and wait until 15 minutes before reinsertion.

Side effects

Like all medicines, Dorzolamide Hydrochloride eye drops can cause side effects, although not everybody gets them.

If you develop allergic reactions including hives, swelling of the face,

lips, tongue, and /or throat which may cause difficulty in breathing or swallowing, you should stop using this medicine and seek immediate medical advice.

The following side effects may be seen with Dorzolamide Hydrochloride eye drops:

Very common

- Burning and stinging of the eyes

Common

- disease of the surface layer of the eye with sore eye and blurred vision, inflammation or swelling of the surface layer of the eye(s) and possible inflammation of the eyelid(s) and/or skin around the eye(s), watering or itching of the eye(s), blurred vision, effects in the surface of the eye
- nausea, bitter taste
- weakness/fatigue
- headache

Uncommon

- inflammation of the middle layer of the eye

Rare

- swelling of the surface layer of the eye(s), separation of part of the lining of the eye due to a build up of fluid which may be accompanied by visual changes /disturbances (following eye surgery), low pressure in the eye, redness of the eye(s), eye pain, crusting of the eyelid(s), temporary shortsightedness (which stops when the medicine is discontinued)
- throat irritation, dry mouth
- hypersensitivity: signs and symptoms of local reactions (affecting the eyelids) and general allergic reactions such as rash, hives, itching, in rare cases possible swelling on the lips, eyes and mouth, shortness of breath and more rarely wheezing
- dizziness, numbness/tingling sensation
- formation of kidney stone in the urinary system
- skin inflammation

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to The National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.moh.gov.my (Consumers → Reporting → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Storage and Disposal of Dorzolamide Hydrochloride eye drops

- Storage

Keep out of reach and sight of children.

Do not use Dorzolamide Hydrochloride eye drops after the expiry date which is stated on the bottle label and the carton after EXP. The expiry date refers to the last day of the month.

Keep the bottle in the outer carton in order to protect from light. Store below 30°C.

Dorzolamide Hydrochloride eye drops should be used within 28 days after the bottle is first opened. Therefore, you must throw away the bottle 4 weeks after you first opened it, even the solution is left. To help you remember, write down the date that you opened it in the space on the carton,

- Disposal

Medicines should not be disposed of via wastewater or household waste.

Ask your pharmacist how to dispose of medicines no longer required.

These measures will help to protect the environment.

Product Description

- What it looks like

Clear, colourless, slightly viscous solution, practically free from visible particles.

- Ingredients
 - Active ingredient (s)

Dorzolamide Hydrochloride.
 - Inactive ingredients

Mannitol, hydroxyethyl cellulose, benzalkonium chloride (as preservative), sodium citrate, sodium hydroxide and water for injection.
- MAL number(s):

MAL13125012AZ

Manufacturer

FDC Limited

Plot No.B-8, M.I.D.C. Industrial Area, Waluj, Aurangabad 431 136, Maharashtra State, India.

Product Registration Holder

UNIMED SDN BHD

No.53 Jalan Tembaga SD 5/2B, Bandar Sri Damansara, 52200 Kuala Lumpur.

Serial Number

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