

Patient Information Leaflet

SCHEDULING STATUS

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DORZOLAMIDE ADCO, 20 mg, eye drops solution Dorzolamide

Read all of this leaflet carefully before you start taking / using / are given DORZOLAMIDE ADCO

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- DORZOLAMIDE ADCO has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What DORZOLAMIDE ADCO is and what it is used for
2. What you need to know before you use DORZOLAMIDE ADCO
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1. What DORZOLAMIDE ADCO is and what it is used for

DORZOLAMIDE ADCO is a preservative free eye drop that contains dorzolamide. Dorzolamide belongs to a group of medicines called "carbonic anhydrase inhibitors". DORZOLAMIDE ADCO is prescribed to lower raised pressure in the eye and to treat glaucoma. DORZOLAMIDE ADCO can be used alone or in addition to other medicines which lower the pressure in the eye (so-called beta-blockers). DORZOLAMIDE ADCO is also used in the short-term treatment of glaucoma in children, either in combination with other medicine (called beta-blockers) or alone.

2. What you need to know before you use DORZOLAMIDE ADCO

Do not take DORZOLAMIDE ADCO

- If you are hypersensitive (allergic) to dorzolamide or any other component of DORZOLAMIDE ADCO. (see section 6)
- If you have severe kidney impairment or problems, or a prior history of kidney stones.

Warnings and precautions

Talk to your doctor or health care provider before using DORZOLAMIDE ADCO.
Take special care with DORZOLAMIDE ADCO:

- If you have or have had any allergies or allergic reactions (including hives, swelling of the face, lips, tongue, and/or throat which may cause difficulty in breathing or swallowing) which required hospital treatment.

If you develop any eye irritation or any new eye problems such as redness of the eye or swelling of the eyelids, contact your doctor or health care provider immediately.

If you suspect that DORZOLAMIDE ADCO is causing an allergic reaction or hypersensitivity (for example, skin rash, severe skin reaction, or redness and itching of the eye), stop using DORZOLAMIDE ADCO and contact your doctor or health care provider immediately.

DORZOLAMIDE ADCO has not been studied in patients with hepatic impairment and should therefore be used with caution in such patients.

Children

DORZOLAMIDE ADCO has been studied in infants and children less than 6 years of age who have raised pressure in the eye(s) or have been diagnosed with glaucoma. For more information, talk to your doctor.

Other medicines and DORZOLAMIDE ADCO

Always tell your health care provider if you are taking any other medicine.

(This includes all complementary or traditional medicines.)

DORZOLAMIDE ADCO can affect or be affected by other medicines you are using, including other eye drops for the treatment of glaucoma. Tell your doctor or health care provider if you are using, have recently used or might use any other medicines, particularly if you are taking another carbonic anhydrase inhibitor such as acetazolamide, or a sulpha medication.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking DORZOLAMIDE ADCO.

Pregnancy

Do not use DORZOLAMIDE ADCO if you are pregnant unless your doctor considers it necessary

Breastfeeding

Do not use DORZOLAMIDE ADCO if you are breastfeeding. Dorzolamide may get into your milk. Ask your doctor for advice before taking any medicine during breastfeeding.

Driving and using machines

There are side effects associated with DORZOLAMIDE ADCO, such as dizziness and blurred vision, which may affect your abilities to perform or execute tasks or activities such as driving, riding, flying, sailing or operating machines/equipment.

It is not always possible to predict to what extent DORZOLAMIDE ADCO may interfere with your daily activities. Patients should ensure that you do not engage in the above activities until you are aware of the measure to which DORZOLAMIDE ADCO affects them.

3. How to use DORZOLAMIDE ADCO

Do not share medicines prescribed for you with any other person.

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

When DORZOLAMIDE ADCO is used alone, the recommended dose is one drop in the affected eye(s) in the morning, in the afternoon and in the evening.

If your doctor has recommended you to use DORZOLAMIDE ADCO with a beta-blocker eye drop to lower eye pressure, then the recommended dose is one drop of DORZOLAMIDE ADCO in the affected eye(s) in the morning and in the evening.

If you are using DORZOLAMIDE ADCO with another eye drop, the drops should be instilled at least 10 minutes apart.

If you are changing from another antiglaucoma eye drop to DORZOLAMIDE ADCO, discontinue the other medicine and only start DORZOLAMIDE ADCO the following day.

Your doctor will tell you how long your treatment with DORZOLAMIDE ADCO will last. Do not stop treatment early without discussing it with your doctor. If you have the impression that the effect of DORZOLAMIDE ADCO is too strong or too weak, tell your doctor or pharmacist.

If you use more DORZOLAMIDE ADCO than you should

If you put too many drops in your eye or swallow any of the contents of the container, among other effects, you may:

- become sleepy or feel tired;
- feel light-headed (dizzy);
- experience abnormal dreams;
- experience headaches;
- feel nauseous; or
- experience difficulty or discomfort in swallowing.

In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take / missed a dose of DORZOLAMIDE ADCO

If you miss a dose, use 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 take a double dose to make up for forgotten individual doses.

If you stop taking/using DORZOLAMIDE ADCO

Don't stop taking DORZOLAMIDE ADCO without talking to your doctor first.

4. Possible side effects

DORZOLAMIDE ADCO can have side effects.

Not all side effects reported for DORZOLAMIDE ADCO are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking DORZOLAMIDE ADCO, please consult your health care provider for advice.

If any of the following happens, stop using DORZOLAMIDE ADCO and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;

These are all very serious side effects. If you have them, you may have had a serious reaction to DORZOLAMIDE ADCO. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- changes in the way your heart beats, for example, if you notice it is beating faster,
- shortness of breath/difficulty breathing.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Itching, burning, stinging and tearing of the eye(s).
- Redness or inflammation in the white part of the eye (conjunctivitis).
- Blurred vision.
- Superficial punctate keratitis (the eyes become red, watery, and sensitive to light, and vision may decrease somewhat).
- Inflammation of the eyelids in which they become red, irritated and itchy.
- Bitter taste
- Headache.
- Feeling sick, also called nausea, weakness/tiredness, and fatigue.

Less frequent side effects:

- Allergic reactions including angioedema (swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing), rash, anaphylaxis (severe allergic reaction).
- Shortness of breath, rarely bronchospasm (muscles that line your airways in your lungs tighten, making it hard to breathe and causes wheezing), nosebleeds (epistaxis).
- Rash, contact dermatitis (red, itchy rash caused by direct contact with a medicine or an allergic reaction to it), severe skin reactions (Stevens-Johnson syndrome and toxic

epidermal necrolysis).

- Dizziness, tingling or numbness of the hands or feet (paraesthesia).
- Temporary short sightedness which may resolve when treatment is stopped, detachment of the layer below the retina that contains blood vessels (choroidal detachment) following from filtration surgery.
- Eyelid crusting, low pressure in the eye (ocular hypotony), inflammation of the iris (the colored part of the eye) and of the ciliary body (muscles and tissue involved in focusing the eye).
- Kidney stones (urolithiasis).
- Dry mouth, throat irritation.

Side effects of an unknown frequency:

- Foreign body sensation in eye (feeling that there is something in your eye).
- A type of heart rhythm disorder (palpitations).
- Difficulty breathing (Dyspnoea)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of DORZOLAMIDE ADCO.

5. How to store DORZOLAMIDE ADCO

Store all medicines out of reach of children.

Store at or below 25 °C.

DORZOLAMIDE ADCO should not be used more than 28 days after opening.

Do not use after the expiry date stated on the container label and the carton.

Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What DORZOLAMIDE ADCO contains

The active substances are dorzolamide.

Each mL contains dorzolamide hydrochloride equivalent to 20 mg dorzolamide.

The other ingredients are hydroxy ethyl cellulose, mannitol, sodium citrate, sodium hydroxide, and water for injection.

DORZOLAMIDE ADCO is preservative free.

What DORZOLAMIDE ADCO looks like and contents of the pack

DORZOLAMIDE ADCO is a clear, slightly viscous, colourless, aqueous solution.

DORZOLAMIDE ADCO eye drops solution is packed in a 11 mL white opaque LDPE bottle with a white HDPE Novelia nozzle/cap subassembly (containing a silicone valve, spring and plug), closed with a white HDPE screw cap and packed in an outer carton. Each bottle contains 5 mL in a 11 mL bottle.

Holder of Certificate of Registration

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