PATIENT INFORMATION LEAFLET

OCUDOR CO

SCHEDULING STATUS:

S3

OCUDOR CO eye drop solution

Dorzolamide hydrochloride and timolol maleate

Contains Preservative: Benzalkonium chloride, 0,0075 % (m/v)

Read all of this leaflet carefully before you start using OCUDOR CO

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist, nurse or other healthcare provider.
- OCUDOR CO 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 OCUDOR CO is and what it is used for
2. What you need to know before you take OCUDOR CO
3. How to take OCUDOR CO
4. Possible side effects
5. How to store OCUDOR CO
6. Contents of the pack and other information

1. What OCUDOR CO is and what it is used for

The active substances are dorzolamide hydrochloride and timolol maleate.

Dorzolamide belongs to a group of medicines called carbonic anhydrase inhibitors and Timolol belongs to a group of medicines called Nonselective beta-adrenergic receptor blocking medicines.

OCUDOR CO eye drops are used to reduce high pressure in the eye in the treatment of glaucoma and ocular hypertension.

2. What you need to know before you use OCUDOR CO

Do not use OCUDOR CO:

- if you are hypersensitive (allergic) to dorzolamide, timolol, sulphonamides or any of the other ingredients of OCUDOR CO (see section 6)
- if you currently have or have a history of breathing problems such as asthma or obstructive lung disease (severe lung disease which may cause wheeziness, difficulty in breathing and/or long-standing cough)
- if you have a slow or irregular heartbeat or serious heart problems
- if you have kidney disease or problems, or a prior history of kidney stones
- if you are pregnant or breastfeeding (see **Pregnancy and breastfeeding**)
- if you are wearing contact lenses.

Warnings and precautions

Take special care with OCUDOR CO:

Tell your doctor if you currently have or have had in the past any of the following medical problems:

- heart problems
- poor blood circulation such as Raynaud's disease or Raynaud's syndrome
- asthma or other breathing problems
- if you suspect that OCUDOR CO is causing a severe allergic reaction (e.g. skin rash, severe skin reaction or itching), stop using OCUDOR CO and contact your doctor at once
- if you develop any eye irritation or any new eye problems such as redness of the eye or swelling of the eyelids, stop using OCUDOR CO and contact your doctor at once
- if you have now or have had in the past any eye problems, eye disease or eye surgeries

- if you use emergency epinephrine (adrenaline) for allergic reactions, since OCUDOR CO may cause you to be unresponsive to your usual dose of epinephrine
- if you have a tumour of the adrenal glands
- if you have kidney or liver problems
- if you have an overactive thyroid gland, as OCUDOR CO may hide the signs of this disease
- if you suffer from diabetes. OCUDOR CO may mask the signs and symptoms of low blood sugar
- before you have an operation, tell your doctor that you are using OCUDOR CO as this medicine may alter the effects of the anaesthetic
- if you have muscle weakness or have been diagnosed as having myasthenia gravis
- if you wear contact lenses (see OCUDOR CO contains benzalkonium chloride).

Children

OCUDOR CO should not be used in children less than 2 years of age. There is limited experience with OCUDOR CO in children between 2 and 6 years of age. However, safety and efficacy data with this solution are insufficient to recommend a safe and effective dose.

Other medicines and OCUDOR CO

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

Tell your doctor if you take any of the following medicines:

- epinephrine (adrenaline) as emergency medication for allergic reactions
- medicines used to treat high blood pressure or heart problems (e.g. calcium channel blockers, beta-blockers, amiodarone, digoxin, parasympathomimetics, guanethidine, narcotics, monoamine oxidase (MAO) inhibitors, clonidine or quinidine)
- anti-depressants, such as fluoxetine or paroxetine

- another carbonic anhydrase inhibitor
- diabetic medicines to lower blood sugar
- other eye drops to reduce eye pressure.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before using OCUDOR CO.

Do not use OCUDOR CO if you are pregnant or breastfeeding.

Driving and using machines

There are side effects associated with OCUDOR CO, such as dizziness and problems with vision, which may affect your ability to drive and/or operate machinery. Do not drive or operate machinery until you feel well and your vision is clear.

It is not always possible to predict to what extent OCUDOR CO may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which OCUDOR CO affects them.

OCUDOR CO contains benzalkonium chloride

Do not use OCUDOR CO eye drops whilst wearing contact lenses. OCUDOR CO contains the preservative benzalkonium chloride which may be absorbed by soft contact lenses, causing eye irritation and discolouration of the contact lenses. Remove your contact lenses before using OCUDOR CO and wait 15 minutes before replacing your lenses.

Your doctor will advise you to have regular eye checks whilst taking OCUDOR CO, since the preservative benzalkonium chloride may damage the cornea of the eye, especially if OCUDOR CO is used over a long period.

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 health care provider.

3. How to use OCUDOR CO

Do not share medicines prescribed for you with any other person.
Always use OCUDOR CO exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The usual dose is one drop of OCUDOR CO in the affected eye(s) in the morning and in the evening.
If you use OCUDOR CO with another eye medicine, wait at least 10 minutes after using OCUDOR CO before you use the other eye medicine.

Your doctor will tell you how long your treatment with OCUDOR CO will last.
If you have the impression that the effect of OCUDOR CO is too strong or too weak, tell your doctor or pharmacist.

Instructions for the use of OCUDOR CO:

Do not use OCUDOR CO if the tamper-proof seal ring on the dispenser neck is broken before you first use it.

1. Wash your hands.
2. Twist off the cap.
3. Tilt your head back and look upwards.
4. Gently pull down your lower eyelid, until there is a “pocket” between the eyelid and your eye. The drop will go in here.
5. Turn the dispenser upside down and gently squeeze the dispenser until it releases one drop of solution into each eye that you are treating. If a drop misses your eye, try again.

6. Let go of the lower eyelid and close your eye for about 30 seconds.

To prevent infections and to avoid eye injury, do not let the tip of the dispenser touch your eye or anything else. Put the cap back on the dispenser immediately after use.

If you use more OCUDOR CO than you should

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

If you forget to use OCUDOR CO

If you forget to use OCUDOR CO, use a single drop as soon as you remember. 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 two drops to make up for a forgotten dose.

If you stop using OCUDOR CO

Do not stop OCUDOR CO treatment early because your eye pressure may return.
If you have an over active thyroid, and you stop using OCUDOR CO abruptly, you may experience worsening of your symptoms.

4. Possible side effects

OCUDOR CO can have side effects.
Not all side effects reported for OCUDOR CO are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while using OCUDOR CO, please consult your doctor, pharmacist or other healthcare professional for advice.

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

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

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to OCUDOR CO. 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:

- severe peeling and swelling of the skin, blistering of the skin, mouth, eyes, genitals, and fever; 'skin rash' with pink-red blotches especially on palms of hands and soles of feet, which may blister (Stevens-Johnson syndrome or toxic epidermal necrolysis)
- extreme tiredness, painful or swollen joints, headaches, rash on cheeks and nose (all signs of an immune system disorder known as Systemic Lupus Erythematosus)
- you feel tired and weak, you have an irregular heart rate, pale skin or skin rash, infection or unusual bruising or bleeding (signs of possible problems with your blood)
- sudden numbness or weakness of the face, arm or leg, especially on one side of the body (you may have experienced a stroke)
- heart problems such as changes to your heart beat (it may become slow, fast or irregular), chest pain, heart disease with shortness of breath and swelling of feet and legs due to fluid build up
- severe breathing problems or pain when breathing
- liver failure (symptoms include yellowing of the skin or whites of the eyes, stomach pain or swelling).

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:

- headache
- eye problems such as blurred vision, burning and stinging eyes, itching, watery, red or sore eyes which are sensitive to light, eye pain or swelling or crusting of the eyelids, dry eyes, blurred vision, dry eye(s), inflammation of the iris
- sinus problems (headache or facial pain)
- bitter, metallic taste in your throat and mouth, changes in taste perception, nausea (feeling sick or being sick)
- lack of energy, feeling weak or tired

Less frequent side effects:

- depression, insomnia, memory loss, nightmares, hallucinations, confusion
- dizziness, tingling or numbness of the hands or feet, decreased sex drive, an increase in signs and symptoms of myasthenia gravis (a muscle disorder)
- corneal erosion (damage to the front layer of the eyeball), swelling and/or irritation in and around the eye(s), decreased corneal sensitivity (not realizing of getting something in the eye(s) and not feeling pain), pain in the eye(s), detachment of the layer below the retina that contains blood vessels following filtration surgery which may cause visual disturbances including refractive changes (in some cases due to withdrawal of medication to treat excessive contraction of the pupil of the eye), eye pain, eyelid crusting, swelling of the cornea (with symptoms of visual disturbances), low pressure in the eye, drooping of the eyelids, double vision, temporary short sightedness
- ringing in the ears (tinnitus)
- shortness of breath, blocked or runny nose, nose bleeds, cough
- cramping pain in the legs, cold and/or swollen hands and feet, you may feel dizzy, lightheaded or faint due to low blood pressure

- dry mouth, throat irritation, indigestion, diarrhoea
- dry, red or flaky skin, skin rash, itchy skin, hair loss, white silvery coloured appearance (psoriasiform rash) or worsening of psoriasis
- kidney stones (you may notice blood in your urine or experience pain when urinating)
- Peyronie's disease (which may cause a curvature of the penis), decreased libido

The following side effects have been reported but the frequency for them to occur is not known:

- increased thirst or frequent urination, sweaty and pale skin (signs of either high or low blood sugar levels)
- foreign body sensation in eye (feeling that there is something in your eye)
- increased blood pressure
- stomach pain or cramps, constipation, vomiting, difficulty, lower volume, blood in urine, excess urination, or a constant sneed to urinate at night, pain in the scrotum, small bowel obstruction
- excessive sweating
- muscle or joint pain, muscle cramps
- sexual dysfunction, male impotence
- changes to the amount of fats or cholesterol in your blood, or raised liver enzymes, which will be noticed in a blood test.

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. 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 OCUDOR CO. You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za, to ensure safety of the product.

5. How to store OCUDOR CO

Store all medicines out of reach of children.

Store at or below 25 °C. Do not freeze. Protect from light.

Keep dispenser tightly closed and in the carton when not in use.

If opened, use within 28 days.

Do not use after the expiry date stated on 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 OCUDOR CO contains

The active substances are dorzolamide hydrochloride and timolol maleate.

Dorzolamide belongs to a group of medicines called carbonic anhydrase inhibitors and Timolol belongs to a group of medicines called Nonselective beta-adrenergic receptor blocking medicines.

The other ingredients are benzalkonium chloride, hydroxyethyl cellulose, mannitol, sodium citrate (for pH-adjustment), sodium hydroxide (for pH-adjustment) and water for injection.

What OCUDOR CO looks like and contents of the pack

Clear, slightly viscous, colourless aqueous solution.

White opaque polyethylene 10 mL dispenser, with a sealed dropper tip, and cap with a tamper-proof seal ring, packed into an outer carton. Each dispenser is filled with 5 mL of solution.

Holder of Certificate of Registration

Pharma Dynamics (Pty) Ltd

1st Floor, Grapevine House, Steenberg Office Park

Silverwood Close

Westlake, Cape Town

7945, South Africa

Tel: + 27 21 707 7000

or 0860-PHARMA (742 762)

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