APPROVED PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

OCUTRA CO eye drop solution

Travoprost and Timolol maleate

OCUTRA CO contains preservatives benzalkonium chloride 0,015 % m/v, boric acid 0,3 % m/v and edetate disodium 0,01 % m/v

Read all of this leaflet carefully before you start using OCUTRA 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.
- OCUTRA 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

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

OCUTRA CO eye drop solution is a combination of two active ingredients (travoprost and timolol). Travoprost is a prostaglandin analogue which works by increasing the outflow of aqueous fluid from the eye, which lowers its pressure. Timolol is a beta blocker which works by reducing the production of fluid within the eye. The two ingredients work together to reduce pressure within the eye.

OCUTRA CO eye drops are used to reduce high pressure in the eye.

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

Do not use OCUTRA CO if:

- if you are hypersensitive (allergic) to travoprost, timolol, or any of the other ingredients of OCUTRA CO (see section 6)

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- you currently have or have a history of breathing problems such as asthma or lung disease
- you have a slow or irregular heartbeat or heart failure
- you are pregnant or breastfeeding (see Pregnancy and breastfeeding).

Warnings and precautions

Take special care with OCUTRA CO:

OCUTRA CO is not recommended for use in children and adolescents under the age of 18 years as the safety of OCUTRA CO in this age group has not been proven.

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

- heart problems
- asthma or other breathing problems
- poor blood circulation such as Raynaud's disease or Raynaud's syndrome
- if you suffer from diabetes. OCUTRA CO may mask the signs and symptoms of low blood sugar
- if you use emergency epinephrine (adrenaline) for allergic reactions, since OCUTRA CO may cause you to be unresponsive to your usual dose of epinephrine

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- if you have muscle weakness or have been diagnosed as having myasthenia gravis
- if you have now or have had in the past any eye problems, eye disease, inflammation of the eyes, dry eyes or eye surgeries
- if you have an overactive thyroid gland, as OCUTRA CO may hide the signs of this disease
- if you have a tumour of the adrenal glands
- if you must have an operation, tell your doctor that you are using OCUTRA CO as this medicine may alter the effects of the anaesthetic
- if you wear contact lenses (see Important information about some of the ingredients of OCUTRA CO).

OCUTRA CO may change the colour of your iris (the coloured part of the eye). This change may be permanent.

OCUTRA CO may increase the length, thickness, colour and/or number of eye lashes. OCUTRA CO may also cause your eyelids, or the skin around your eyes, to darken and may also cause deepening of the upper eyelid (sunken eyes).
OCUTRA CO may be absorbed through the skin and therefore should not be used by women who are pregnant or are attempting to become pregnant. If any of OCUTRA CO comes into contact with the skin, it should be washed off immediately.

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Other medicines and OCUTRA 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:

- medicines used to treat high blood pressure or heart problems (e.g. calcium channel blockers, clonidine, beta-blockers, digoxin, guanethidine or quinidine).
- medicines to treat serious heart rhythm disorders (e.g. amiodarone)
- anti-depressants, called serotonin re-uptake inhibitors
- epinephrine (adrenaline) as emergency medication for allergic reactions
- medicines to treat your diabetes
- other eye drops to reduce eye pressure.

Pregnancy, breastfeeding and fertility

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 OCUTRA CO.

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

Driving and using machines

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OCUTRA CO has minor influence on the ability to drive and use machines.

OCUTRA CO may cause blurred vision, which may affect your ability to drive and/or operate machinery. Do not drive or operate machinery until your vision is clear.

It is not always possible to predict to what extent OCUTRA 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 OCUTRA CO affects them.

OCUTRA CO contains benzalkonium chloride

Do not use OCUTRA CO eye drops whilst wearing contact lenses. OCUTRA 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 OCUTRA CO and wait 15 minutes before replacing your lenses.

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

3. How to use OCUTRA CO

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

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Always take/use OCUTRA CO exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Adults:

The usual dose is one drop of OCUTRA CO in the affected eye(s) in the morning or in the evening. OCUTRA CO should be used at the same time each day.

If you use OCUTRA CO with another eye medicine, wait at least 5 minutes after using OCUTRA CO before you use the other eye medicine.

Instructions for the use of OCUTRA CO:

Immediately before using the dispenser for the first time, remove the protective paper or foil sachet.

Do not use OCUTRA CO if the tamper-proof seal ring on the vial 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.

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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. After using OCUTRA CO, close your eye and press a finger into the corner of your eye, by the nose, for 2 minutes. This helps to stop OCUTRA CO from leaking into your nose and throat.

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.

Your doctor will tell you how long your treatment with OCUTRA CO will last. Do not stop treatment early because your symptoms may return.
If you have the impression that the effect of OCUTRA CO is too strong or too weak, tell your doctor or pharmacist.

If you use more OCUTRA 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 OCUTRA CO

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If you forget to use OCUTRA CO, continue with the next dose as planned. Do not use two drops to make up for a forgotten dose. The dose of OCUTRA CO should not exceed one drop daily in the affected eye(s).

If you stop using OCUTRA CO

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

4. Possible side effects

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

If any of the following happens, stop using OCUTRA 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

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- fainting.

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

- eye surface inflammation with surface damage, eye pain, blurred vision, abnormal vision, reduced vision, tired eyes with pain in eyes and dimness of eyesight, thinning of the eye surface, drooping of the eyelids, vision problems including double vision, inflammation of the eyelid, inflammation of the cornea, detachment of the layer below the retina that contains blood vessels following filtration surgery that could cause visual disturbances
- sudden fever, chills, sore throat and weakness in the limbs (all signs of 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 failure, heart disease with shortness of breath and swelling of ankles, feet or fingers due to fluid build up

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- high blood pressure (you may experience nervousness, sweating, difficulty sleeping or facial flushing).

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:

- eye problems such as abnormal sensation in the eye or eye irritation (e.g. burning and stinging), abnormal growth of eye lashes, excess of blood in white of the eye, itching, red or sore eyes which are sensitive to light.

Less frequent side effects:

- nervousness
- dizziness, headache
- eye or eyelid pain or swelling or crusting of the eyelids, decreased production of tears or dry eyes, eye inflammation or swelling, changes to the skin around the eye or eyelid (reddening), eye colour change, possible problems after eye surgery, pink eye, eye watering, skin darkening (around the eye)
- cough, wheezing or difficulty breathing, discomfort inside of the nose, difficulty speaking, shortness of breath or pain when breathing, drip at back of the throat, throat irritation, pain when swallowing

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- dizzy, feeling lightheaded or faint due to low blood pressure
- raised liver enzymes, which will be noticed in a blood test
- hair loss, dry, itchy, red, or inflamed skin, skin discolouration or patches of dark skin, excessive hair growth, skin rash, flaky or scaly skin, excessive sweating
- pain in the arms, hands, legs or feet
- abnormal coloured urine
- thirst, lack of energy, feeling weak or tired.

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)
- depression, confusion, hallucinations, problems sleeping, memory loss, nightmares, anxiety, insomnia
- seasonal allergies
- dizziness with spinning sensation, ringing in the ears
- headache, fainting, tingling or numbness of the hands or feet, an increase in signs and symptoms of myasthenia gravis (a muscle disorder)
- swelling of the lower limbs, cold, numb and/or swollen hands and feet

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- asthma (mainly in people who already have a breathing disorder)
- a bitter, metallic taste in your throat, stomach pain or cramps, constipation, diarrhoea, dry mouth, indigestion, decreased or lack of urine output, feeling sick or being sick, abdominal pain, reactivation of stomach ulcer
- peeling skin, abnormal hair texture, hair colour change, loss of eyelashes or eyebrows
- muscle or joint pain, muscle cramps
- painful or uncomfortable sensation experienced during urination, loss of bladder control
- sexual dysfunction, decreased sex drive, male impotence (inability to sustain an erection, inability to achieve ejaculation, or both)
- blood pressure or heart changes. Changes to the amount of fats or cholesterol in your blood, 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, pharmacist or nurse. 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 OCUTRA 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 OCUTRA CO

Store all medicines out of reach of children.

Store at or below 25 °C. Do not freeze.

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

If opened, use within 28 days. For external use only.

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 OCUTRA CO contains

The active ingredients are travoprost and timolol maleate.

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Each 1 ml of sterile solution contains 40 micrograms travoprost and timolol maleate equivalent to 5,0 mg timolol.

The other ingredients are

Macrogolglycerol hydroxystearate, mannitol, trometamol and

water for injection.

OCUTRA CO contains preservatives benzalkonium chloride 0,015 % m/v, boric acid 0,3 % m/v and edetate disodium 0,01 % m/v.

What OCUTRA CO looks like and contents of the pack

Clear, colourless solution.

Transparent 5 ml polypropylene vial, sealed with a transparent LDPE dropper and white cap with a tamper-proof seal ring. The vial is enclosed in a white printed aluminium sachet (silver on the inside) and packed into an outer carton. Each vial is filled with 2,5 ml of solution.

Holder of Certificate of Registration

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