

## **Package leaflet: Information for the user**

### **ClaroOpt 20mg/ml + 5mg/ml Eye Drops, Solution**

Dorzolamide / Timolol

**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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

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

#### **1. What ClaroOpt is and what it is used for**

ClaroOpt is a combination of two medicines: dorzolamide and timolol.

- Dorzolamide belongs to a group of medicines called “carbonic anhydrase inhibitors”.
- Timolol belongs to a group of medicines called “beta blockers”.

ClaroOpt is prescribed to lower raised pressure within the eye in the treatment of glaucoma when beta-blocker eye drops used alone are not adequate.

#### **2. What you need to know before you use ClaroOpt**

##### **DO NOT use ClaroOpt eye drops, solution**

- if you are allergic to dorzolamide or timolol, beta-blockers or any of the other ingredients of this medicine (listed in section 6).
- if you have now or have had in past respiratory problems such as asthma, severe chronic obstructive bronchitis (severe lung disease which may cause wheeziness, difficulty in breathing and/or long-standing cough).
- if you have severe kidney problems, or a prior history of kidney stones.
- if you have a disturbance in the pH (acid/alkali balance) of your blood.
- if you have certain heart problems, including certain heart rhythm disturbances producing an abnormally slow heart rate or severe heart failure.

If you think any of these apply to you, do not use ClaroOpt until you have consulted your doctor.

#### **Warnings and precautions**

Talk to your doctor or pharmacist before taking ClaroOpt, especially if you have now or have had in the past:

- coronary heart disease (symptoms can include chest pain [even while resting] or tightness, breathlessness or choking), heart failure, low blood pressure.
- breathing problems, asthma or chronic obstructive pulmonary disease.
- poor blood circulation disease (such as Raynaud’s disease or Raynaud’s syndrome).
- diabetes as timolol may mask signs and symptoms of low blood sugar.
- overactivity of the thyroid gland as timolol may mask signs and symptoms.
- any allergies to a medicine you have taken.

Tell your doctor before you have an operation that you are using Claropt as dorzolamide/timolol may change effects of some medicines used during anaesthesia. There may be a sudden fall in blood-pressure associated with the anaesthetic.

Tell your doctor if you now have or have had liver problems, if you have muscle weakness or have been diagnosed as having myasthenia gravis.

If you develop conjunctivitis (redness and irritation of the eye[s]), swelling of the eye or eyelids, skin rash, or itching in and around the eye contact your doctor immediately. Such symptoms may be due to an allergic reaction or may be a side-effect of Claropt (see section 4 “Possible side effects”).

Tell your doctor if you develop an eye infection, receive an eye injury, have eye surgery, develop other reactions or worsening of symptoms.

If you wear soft contact lenses, it is important that your lenses are removed before using your eye drops and not put back into your eyes until 15 minutes after using your eye drops as the preservative benzalkonium chloride may possibly discolour the contact lenses.

### **Children**

There is limited experience with Claropt in infants and children.

### **Use in elderly**

In studies with dorzolamide/timolol eye drops solution, the effects of dorzolamide/timolol eye drops solution were similar in both elderly and younger patients.

### **Other medicines and Claropt**

Claropt can affect or be affected by other medicines you are using, including other eye drops for the treatment of glaucoma. Tell your doctor if you are using or intend to use medicines to lower blood pressure, heart medicine or medicines to treat diabetes.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is particularly important if any of the following apply to you:

- You are taking antihypertensive medicines which are used to lower high blood pressure or medicines to treat heart disease such as calcium channel blockers and  $\beta$ -blockers or digoxin
- You are taking medicines to treat a disturbed or uneven heartbeat such as quinidine (use to treat some types of malaria as well) or digoxin
- You are using another eyedrop that contains a  $\beta$ -blocker
- 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
- You are taking monoamine oxidase inhibitors (MAOIs) or selective serotonin reuptake inhibitors (SSRIs, e.g. fluoxetine and paroxetine) both of which are used to treat depression or another illness
- You are taking a parasympathomimetic medicine which may have been prescribed to help you pass urine. Parasympathomimetics are also a particular type of medicine which are sometimes used to help restore normal movements through the bowel
- You are taking narcotics such as morphine used to treat moderate to severe pain or if you are taking large doses of acetylsalicylic acid. Although there is no evidence that dorzolamide hydrochloride interacts with acetylsalicylic acid, some other medicines which are related to dorzolamide hydrochloride and which are taken by mouth, have been known to interact with acetylsalicylic acid
- You are taking medicines to treat diabetes or high blood sugar
- You are taking epinephrine (adrenaline).

### **Pregnancy and breast-feeding**

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 taking this medicine.

Do not use Claropt if you are pregnant unless your doctor considers it necessary.

Tell your doctor if you are pregnant or planning to become pregnant.

Do not use Claropt if you are breast-feeding. Timolol may get into your milk.

Tell your doctor if you are breast-feeding or intend to breast-feed.

### **Driving and using machines**

Claropt may cause side effects such as blurred vision in some patients. Do not drive or use any tools or machines until the symptoms have cleared.

### **Claropt contains 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 at least 15 minutes before reinsertion.

### **3. How to use Claropt**

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

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

#### Adults

The usual dose is one drop in the affected eye(s) two times a day, for example in the morning and in the evening.

If you use Claropt with another eye drop, leave at least 10 minutes between putting in Claropt and the other medicine.

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 infections 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.

In order to secure correct dosage - the dropper tip should not be enlarged.

### **Instructions for use**

It is recommended that you wash your hands before putting in your eye drops. It may be easier to apply your eye drops in front of a mirror.

1. Before using the medication for the first time, be sure that the tamper-proof seal on the bottle neck is unbroken. A gap between the bottle and the cap is normal for an unopened bottle.
2. Take off the cap of the bottle.
3. Tilt your head back and gently pull your lower eyelid down to form a small pocket between your eyelid and your eye.



4. Invert the bottle, and squeeze it until a single drop is dispensed into the eye as directed by your doctor. **DO NOT TOUCH YOUR EYE OR EYELID WITH THE DROPPER TIP.**

5. After using Claropt, press a finger into the corner of your eye, by the nose for 2 minutes. This helps to stop dorzolamide/timolol getting into the rest of the body.



6. Repeat steps 3 to 5 with the other eye if instructed to do so by your doctor.  
7. Put the cap back on and close the bottle straight after you have used it.

#### **If you use more Claropt than you should**

It is important to keep to the dose your doctor has prescribed. If you put too many drops in your eye or swallow any of the contents of the bottle, you may feel unwell, for example you may become light-headed, have difficulty breathing, or feel that your heart rate has slowed. If you feel any of the above effects you should seek medical attention immediately.

#### **If you forget to use Claropt**

It is important to use Claropt 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 stop taking Claropt**

If you want to stop using this medicine talk to your doctor first.

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

#### **4. Possible side effects**

Like all medicines, this medicine 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 Claropt and talk to your doctor immediately.

You can usually carry on taking the drops, unless the effects are serious. If you're worried, talk to a doctor or pharmacist. Do not stop using Claropt without speaking to your doctor.

#### **Very common (may affect more than 1 in 10 people):**

Burning and stinging of the eyes, unusual taste

#### **Common (may affect up to 1 in 10 people):**

Redness in and around the eye(s), watering or itching of the eye(s), and effects on the surface of the eye(s), swelling and/or irritation in and around the eye(s), feeling of having something in the eye (corneal erosion), decreased corneal sensitivity (not realising of getting something in the eye and not feeling pain), eye pain, dry eyes, blurred vision, headache, sinusitis (feeling of tension or fullness in the nose), feeling sick, also called nausea, and fatigue

#### **Uncommon (may affect up to 1 in 100 people):**

Dizziness, depression, inflammation of the iris, blurred vision (in some cases due to withdrawal of medication to treat excessive contraction of the pupil of the eye), slow heartbeat, fainting, indigestion, and kidney stones (often marked by a sudden onset of excruciating, cramping pain in their low back and/or side, groin, or abdomen).

**Rare (may affect up to 1 in 1,000 people):**

systemic lupus erythematosus (an immune disease which may cause an inflammation of internal organs), tingling or numbness of the hands or feet, trouble sleeping, nightmares, memory loss, weakening of the muscles, decreased sex drive, stroke, temporary short-sightedness which may resolve when treatment is stopped, development of fluid under the retina (choroidal detachment following filtration surgery), drooping of the eyelids, double vision, eyelid crusting, swelling of the cornea (with symptoms of visual disturbances), low pressure in the eye, ringing noises in your ear, low blood pressure, irregular heartbeat, chest pain, palpitations (a quicker and/or irregular heartbeat), heart attack, congestive heart failure (heart disease with shortness of breath and swelling of the feet and legs due to fluid build-up), oedema (fluid build-up), reduced blood flow to the brain, swelling or coldness of your hands and feet and reduced circulation in your arms and legs, poor blood circulation which makes the toes and fingers numb and change colour ((Raynaud's phenomenon), leg cramps and/or leg pain when walking (claudication), shortness of breath, feeling out of breath, runny or stuffed nose, nose bleed, difficulty in breathing, cough, throat irritation, dry mouth, diarrhoea, contact dermatitis, hair loss, psoriasis or worsening of psoriasis, Peyronie's disease (which may cause a curvature of the penis), weakness/tiredness, generalised allergic reactions including swelling beneath the skin that can occur in areas such as the face (swelling of the lips, eyes and mouth) and limbs, and can obstruct the airway which may cause difficulty swallowing or breathing, wheezing. Hives or itchy rash, localised and generalised rash, itchiness, severe sudden life-threatening allergic reaction.

Like other medicines applied into eyes, timolol is absorbed into the blood. This may cause similar side effects as seen with 'intravenous' and/or 'oral' as applicable beta-blocking agents. Incidence of side effects after topical ophthalmic administration is lower than when medicines are, for example, taken by mouth or injected. Listed side effects include reactions seen within the class of beta-blockers when used for treating eye conditions:

**Not known (frequency cannot be estimated from the available data):**

Low blood glucose levels.

Heart failure.

Abdominal pain, vomiting.

Muscle pain not caused by exercise.

Sexual dysfunction.

**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](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Claropt**

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 bottle label and the carton after EXP:. The expiry date refers to the last day of that month.

This medicinal product does not require any special temperature storage conditions.

Claropt 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 if some solution is left. To help you remember, write down the date that you opened it in the space on the carton.

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 Claropt contains**

The active substances are dorzolamide and timolol. Each ml contains 20 mg dorzolamide (as 22.26 mg of dorzolamide hydrochloride) and 5 mg timolol (as 6.83 mg of timolol maleate).

The other ingredients are Mannitol (E421), Hydroxy Ethyl Cellulose, Benzalkonium Chloride (as a preservative), Sodium Citrate (E331), Sodium Hydroxide (E524) for pH adjustment and Water for injection.

### **What Claropt looks like and contents of the pack**

Your medicine is in the form of a sterile, clear, slightly viscous, colourless aqueous eye drop solution.

Claropt is presented in a white opaque medium density polyethylene bottle with a sealed low density polyethylene dropper tip and a high density polyethylene cap with tamper proof seal, containing 5 ml of the ophthalmic solution.

Pack size: 1, 3 or 6 bottles of 5 ml each.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

Marketing Authorisation Holder:

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

Manufacturer:

Pharmathen S.A., 6 Dervenakion Str., 15351 Pallini, Attiki, Greece

Famar S.A., 63 Agiou Dimitriou Street, 17456 Alimos, Greece

PharmaCoDane ApS, Marielundvej 46A, 2730 Herlev, Denmark

STADA Arzneimittel AG, Stadastrasse 2-18, D-61118 Bad Vilbel, Germany

### **This medicinal product is authorised in the Member States of the EEA under the following names:**

United Kingdom:	Doticol 20 mg/ml + 5 mg/ml eye drops solution
Austria:	Cosostad 20 + 5 mg/ml Augentropfen
Belgium:	Dorzolamide/ timolol EG 20/5mg/ml oogdruppels, oplossing
Luxembourg:	Dorzolamide/ timolol EG 20/5mg/ml collyre en solution
Germany:	Dorzo plus T STADA 20 mg/ml + 5 mg/ml Augentropfen
Denmark:	Costad
Spain:	Dorzolamida/timolol STADA 20 mg/ml + 5 mg/ml colirio en solución
Finland:	Glaukostad comp
France:	Dorzolamide/Timolol EG 20 mg/ml + 5 mg/ml, collyre en solution
Ireland:	Claropt 20 mg/ml + 5 mg/ml eye drops, solution
Italy:	DORZOLAMIDE E TIMOLOLO EG 20 mg/ml + 5mg/ml collirio, soluzione
Netherlands:	Dorzolamide/Timolol CF 20+5 mg/ml, oogdruppels, oplossing
Norway:	Doticol (20+5) mg/ml øyedråber, oppløsning

**This leaflet was last revised in April 2014.**