

PROSTACOM (LATANOPROST 0.05MG/ML AND TIMOLOL 5MG/ML, EYE DROP)

Latanoprost 0.05mg/ml and Timolol 5mg/ml

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What PROSTACOM is used for

Reduction of intraocular pressure (IOP) in patients with open angle glaucoma and ocular hypertension who are insufficiently responsive to topical beta-blockers.

How PROSTACOM works

PROSTACOM contains two medicines: latanoprost and timolol. Latanoprost belongs to a group of medicines known as prostaglandin analogues.

Timolol belongs to a group of medicines known as beta-blockers. Latanoprost works by increasing the natural outflow of fluid from the eye into the bloodstream. Timolol works by slowing the formation of fluid in the eye.

PROSTACOM is used to reduce the pressure in your eye if you have conditions known as open angle glaucoma or ocular hypertension. Both these conditions are linked to an increase in the pressure within your eye, eventually affecting your eyesight. Your doctor will usually prescribe you PROSTACOM when other medicines have not worked adequately.

Before you use PROSTACOM

When you must not use it

Do not use PROSTACOM Drop:

- if you are allergic (hypersensitive) to either of the medicines in PROSTACOM (latanoprost or timolol), beta-blockers, or any of the other ingredients of PROSTACOM.
- if you have or have had in the 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 serious heart problems or heart rhythm disorders
- if you are pregnant (or trying to become pregnant)
- if you are breastfeeding

Before you start to use it

Talk to your doctor or pharmacist before using PROSTACOM if you have now or have had in the past:

- Coronary heart disease – symptoms can include chest pain or tightness, breathlessness or choking, heart failure, low blood pressure (hypotension)
- Disturbances of heart rate such as slow heart beat (bradycardia)
- Breathing problems, asthma or chronic obstructive pulmonary disease (lung disease which may cause wheeziness, difficulty in breathing and/or long standing cough)
- Poor blood circulation disease (peripheral arterial disease such as Raynaud's disease or Raynaud's syndrome)
- Diabetes as Timolol may mask signs and symptoms of low blood sugar
- Over activity of the thyroid gland as Timolol may mask signs and symptoms
- You are about to have any kind of eye surgery (including cataract surgery) or have had any kind of eye surgery in the past
- You suffer from eye problems (such as eye pain, eye irritation, eye inflammation or blurred vision)
- You know that you suffer from dry eyes
- You wear contact lenses. You can still use PROSTACOM but follow the instructions for contact lens wearers.
- You know that you suffer from angina (particularly a type known as Prinzmetal angina).
- You know that you suffer from severe allergic reactions that would usually require hospital treatment.
- You have suffered or are currently suffering from a viral infection of the eye

caused by the herpes simplex virus (HSV).

Tell your doctor before you have an operation that you are using PROSTACOM as Timolol may change effects of some medicines used during anesthesia.

Taking other medicines

PROSTACOM 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 intent to use medicine to lower blood pressure, heart medicine or medicines to treat diabetes. 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, speak to your doctor or pharmacist if you know that you are taking any of the following types of medicine:

- Prostaglandins, prostaglandin analogues or prostaglandin derivatives
- Beta-blockers
- Epinephrine
- Drugs used to treat high blood pressure such as oral calcium channel blockers, guanethidine, antiarrhythmic, digitalis glycosides or Parasympathomimetics.
- Quinidine (used to treat heart conditions and some types of malaria)
- Antidepressants known as fluoxetine and paroxetine

How to use PROSTACOM

How much to use

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

The usual dosage for adults (including the elderly) is one drop once a day in the affected eye(s).

Use in children

Safety and effectiveness in children have not been established.

Contact lens wearers

If you wear contact lens, you should

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remove them before using PROSTACOM. After using PROSTACOM you should wait 15 minutes before putting your contact lenses back in.

- When to use it

Use as instructed by your doctor.

- How long to use it

Use PROSTACOM as instructed by your doctor until your doctor tells you to stop.

- If you forget to use it

Carry on with the usual dosage at the usual time. Do not take a double dose to make up to the dose you have forgotten. If you are unsure about anything talk to your doctor or pharmacist.

- If you use too much (overdose)

If you put too many drops in your eye you may experience some minor irritation in your eye and your eyes may water and turn red.

This should pass but if you are worried contact your doctor for advice.

If you swallow PROSTACOM accidentally you should contact your doctor for advice. If you swallow a lot of PROSTACOM you may feel sick, have stomach pains, feel tired, flushed and dizzy and start to sweat.

While you are using it

- Things you must do

Instructions for use:

Take your medicine exactly as your doctor has told you. Tell all the doctors, dentists and pharmacists treating you that you are taking PROSTACOM. Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give PROSTACOM to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

When you use PROSTACOM you might have blurred vision, for a short time. If this happens to you, do not drive or use any tools or machines until your vision becomes clear again.

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

You can usually continue to use the drops, unless the effects are serious. If you're worried, talk to a doctor or pharmacist.

The frequency of possible side effects listed below is defined using the following convention: very common, common and uncommon

Listed below are the known side effects of using PROSTACOM. The most important side-effect is the possibility of a gradual, permanent change in your eye colour. It is also possible that PROSTACOM might cause serious changes in the way your heart works. If you notice changes in your heart rate or heart function you should speak to a doctor and tell them you have been using PROSTACOM.

The following are known side effects of using PROSTACOM:

Very common:

A gradual change in your eye colour by increasing the amount of brown pigment in the coloured part of the eye known as the iris is likely to happen if you have mixed-colour eyes (blue-brown, grey-brown, yellow-brown or green-brown).

Any changes in your eye colour may take years to develop. The colour change may be permanent and may be more noticeable if you use PROSTACOM in only one eye. There appears to be no problems associated with the change in eye colour. The eye colour change does not continue

after PROSTACOM treatment is stopped.

Common:

Eye irritation (a feeling of burning, grittiness, itching, stinging or the sensation of a foreign body in the eye) and eye pain.

Uncommon:

- Headache
- Redness of the eye, eye infection (conjunctivitis), blurred vision, watery eyes, inflammation of the eyelids, irritation or disruption of the surface of the eye
- Skin rashes or itching (pruritus)

If you get any side effects talk to your doctor. This includes any possible side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website npra.moh.gov.my (Public → Reporting Medicinal Problems / Side Effects / AEFI).

Storage and Disposal of PROSTACOM

- Storage

Keep out of the reach and sight of children. Store between 2°C to 8°C. Protect from light. Once opened the vial may be stored at room temperature below 25°C. Use the solution within 28 days after opening the bottle

- Disposal

Once opened, you must discard the bottle with any remaining contents - after 28 days. Otherwise, there is a risk of eye infection. 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.

Product Description

- What it looks like

PROSTACOM is a colourless solution.

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Latanoprost 0.05mg/ml and Timolol 5mg/ml

- Ingredients

- Active ingredient(s)

Each ml contains:

Latanoprost 50 mcg.

Timolol Maleate 6.8 mg equivalent to

Timolol 5 mg.

- Inactive ingredients

Benzalkonium chloride, Sodium chloride,
Sodium dihydrogen phosphate
monohydrate, Disodium phosphate
anhydrous, Water for injection and either
Hydrochloric acid or Sodium hydroxide

- MAL Number

MAL*****

Manufacturer and Product Registration Holder

Manufacturer

INDOCO REMEDIES LTD,

Plant II, L-32, 33 & 34, Verna Industrial
Area, Verna, Goa – 403 722, INDIA.

Product Registration Holder

Arms Pharma Sdn. Bhd.

22-1, Jalan PJU 5/20D,

The Strand, 47810 Kota Damansara,
Selangor D.E., MALAYSIA

Date of revision

26/04/2019

Serial Number

NPRA (R2) 19/80