IOPROST LATANOPROST EYE DROPS SOLUTION

Latanoprost (0.005% w/v)

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What IOPROST is used for

IOPROST is used to treat conditions known as open angle glaucoma and ocular hypertension in adults. Both of these conditions are linked with an increase in the pressure within your eye, eventually affecting your eye sight.

IOPROST is also used to treat increased eye pressure and glaucoma in all ages of children and babies.

How IOPROST works

IOPROST belongs to a group of medicines known as prostaglandin analogues. It works by increasing the natural outflow of fluid from inside the eye into the bloodstream.

Before you use IOPROST

- *When you must not use it*

Do not use IOPROST if you are

- Allergic (hypersensitive) to latanoprost or any of the other ingredients of IOPROST.
- Pregnant or trying to become pregnant
- Breast feeding

- *Before you start use it*

IOPROST can be used in adult men and women (including the elderly) and in children from birth to 18 years of age. IOPROST has not been investigated in prematurely born infants (less than 36 weeks gestation).

Talk to your doctor or the doctor treating your child or your pharmacist before you use IOPROST or before you give this to your child if you think any of the following apply to you or your child:

- If you or your child are about to have or have had eye surgery (including cataract surgery)
- If you or your child suffer from eye problems (such as eye pain, irritation or inflammation, blurred vision)
- If you or your child suffers from dry eyes
- If you or your child have severe asthma or the asthma is not well controlled
- If you or your child wear contact lenses. You can still use IOPROST, but follow the instruction for contact lens wearers in Section 3
- If you have suffered or are currently suffering from a viral infection of the eye caused by the herpes simplex virus (HSV)

Pregnancy and lactation

Do not use IOPROST when you are pregnant. Tell your doctor immediately if you are pregnant, think you are pregnant, or are planning to become pregnant.

Do not use IOPROST when you are breast-feeding.

- *Taking other medicines*

IOPROST will interact with two or more prostaglandins (a hormone like substance that have important functions in the body eg: decreasing eye pressure), prostaglandin analogues (molecules which are manufactured to exert similar effects like prostaglandin) or prostaglandin derivatives (molecules manufactured from prostaglandin).

IOPROST may interact with other medicines. Please tell your doctor, the doctor treating your child or pharmacist if you or your child are taking or have taken any other medicines including those medicines (or eye drops) obtained without a prescription.

If you use IOPROST with other eye drops Wait at least 5 minutes between using IOPROST and taking other eye drops

How to use IOPROST

How much to use

Always use IOPROST exactly as your doctor or the doctor treating your child has told you. You should check with your doctor or the doctor treating your child or pharmacist if you are not sure.

The usual dosage for adults (including the elderly) and children is one drop once a day in the affected eye(s). The best time to do this is in the evening.

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- *How long to use it*

Use IOPROST as instructed by your doctor or by the doctor treating your child until they tell you to stop.

If you stop using IOPROST You should speak to your doctor or the doctor treating your child if you want to stop taking IOPROST.

- *If you forget to use it*

Carry on with the usual dosage at the usual time. Do not use a double dose to make up for 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 into the eye, it may lead to some minor irritation in the eye and the eyes may water and turn red. This should pass, but if you are worried contact your doctor or the doctor treating your child for advice.

Contact your doctor as soon as possible if you or your child swallows IOPROST accidentally.

While you are using it

- *Things you must do*

Contact lens wearers

If you or your child wears contact lenses, they should be removed before using IOPROST. After using IOPROST you should wait 15 minutes before putting the contact lenses back into the eye.

Instructions for use

1. Wash your hands and sit or stand comfortably.
2. Unscrew the protective cap. The protective cap should be retained.
3. Use your finger to gently pull down the lower eyelid of your affected eye.
4. Place the tip of the bottle close to, but not touching your eye.
5. Squeeze the bottle gently so that only one drop goes into your eye, then release the lower eyelid.
6. Press a finger against the corner of the affected eye by the nose. Hold for 1 minute whilst keeping the eye closed.
7. Repeat in your other eye if your doctor has told you to do this.
8. Put the protective cap back on the bottle.

- *Things you must not do*

Important information on some ingredient in IOPROST

IOPROST contains a preservative called benzalkonium chloride. This preservative may cause eye irritation or disruption to the surface of the eye. Benzalkonium chloride can be absorbed by contact lenses and is known to discolour soft contact lenses. Therefore, avoid contact with soft contact lenses.

- *Things to be careful of*

Driving and using machines

When you use IOPROST 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, IOPROST can cause side effects, although not everybody gets them. Tell your doctor immediately if you experience any of the following symptoms after taking this medicine as the symptoms can be severe.

Very common effects

- 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. If you have mixed-colour eyes (blue-brown, grey-brown, yellow-brown or green-brown) you are more likely to see this change than if you have eyes of one colour (blue, grey, green or brown eyes). Any changes in your eye colour may take years to develop although it is normally seen within 8 months of treatment. The colour change may be permanent and may be more noticeable if you use IOPROST 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 IOPROST treatment is stopped.
- Redness of the eye.
- Eye irritation (a feeling of burning, grittiness, itching, stinging or the sensation of a foreign body in the eye).
- A gradual change to eyelashes of the treated eye and the fine hairs around the treated eye, seen mostly in people of Japanese origin. These changes involve an increase of the colour (darkening), length, thickness and number of your eye lashes.

Common effects

- Irritation or disruption to the surface of the eye, eyelid inflammation (blepharitis) and eye pain.

Side effects seen more often in children compared to adults are: runny itchy nose and fever.

If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please contact you doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of IOPROST

- *Storage*

  Keep out of the reach and sight of children.

  Do not use IOPROST after the expiry date which is stated on the carton and bottle. The expiry date refers to the last day of that month.

  Protect from light. Store between 2°C to 8°C.

  Use this solution within one month after opening the container.

- *Disposal*

  Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- *What it looks like*

Clear, colourless solution.

- *Ingredients*

  - Active ingredient

  The active substance is 0.005% (50 micrograms/ml) latanoprost.

  - Inactive ingredients

  Benzalkonium chloride, sodium chloride, monobasic sodium phosphate (monohydrate), dibasic sodium phosphate and water for injection.

- *MAL number(s):*

MAL14055152AZ

Manufacturer

DC Limited
B-8, MIDC Area, Waluj, Aurangabad – 431 136, India.

Product Registration Holder

Unimed Sdn Bhd
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