OptaProst Ophthalmic Solution 0.005% $^{W}/_{V}$

Latanoprost (0.05 mg/ml)

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What OptaProst is used for

OptaProst is used to treat conditions known as open angle glaucoma, chronic angle closure glaucoma and ocular hypertension. All of these conditions linked with an increase in the pressure within your eye, eventually affecting your eye sight.

OptaProst is also used to treat increased eye pressure and glaucoma in children.

How OptaProst works

OptaProst contains Latanoprost which is 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 and reduce the pressure in the eye.

Before you use OptaProst

- *When you must not use it*

If allergic (hypersensitive) to the Latanoprost or to any of the other ingredients of OptaProst

If you are not sure whether you should start taking this medicine, talk to your doctor or pharmacist.

- *Before you start to use it*

Discuss with your doctor or pharmacist if:

- 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 or eye inflammation or blurred vision);
- You suffer from dry eyes;
- You wear contact lenses. You should remove the contact lenses before using OptaProst and wait for 15 minutes before putting your contact lenses.
- You use other eye drops. Wait at least 5 minutes between using OptaProst and taking other eye drops.
- You suffered or are currently suffering from a viral infection of the eye caused by the herpes simplex virus (HSV)

Pregnancy and lactation

Do not take OptaProst if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take OptaProst if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- *Taking other medicines*

Tell your doctor if you are taking any other medicines as below:

- Any others prostaglandins (a hormone like substance that have important functions in the body i.e. decreasing eye pressure), prostaglandin analogs (molecules which are manufactured to exert similar effects like prostaglandins) or prostaglandin derivatives (molecules manufactured from prostaglandin)
- Thimerosal (preservative used in some vaccines)

How to use OptaProst

- *How much to use*

Usual dose is one drop, once a day in the affected eye(s). Optimal effect is obtained if it is administered in the evening.

Do not use OptaProst more than once a day, because it will reduce the effectiveness of the treatment.

- *When to use it*

Use as directed by your doctor or pharmacist.

- *How long to use it*

Continue taking OptaProst for as long as your doctor or pharmacist recommends.

- *If you forget to use it*

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose.

Do not take a double dose to make up for the missed dose.

- *If you use too much (overdose)*

If overdosage occurs, treatment should be symptomatic.

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- *Things you must do*

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking OptaProst.

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 OptaProst to anyone else, even if they have the same symptoms or condition as you.

- *Things to be careful of*

This product contains benzalkonium chloride, which may be absorbed by contact lenses.

Driving and using machines

This medicine may affect your ability to drive or use machines. Your vision may become blurred for a short time.

Side effects
Like all medicines, OptaProst can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

- Infection & infestation: Herpetic keratitis* (Viral infection of the eye caused by the herpes simplex virus)
- Nervous system disorders: Dizziness*; headache*
- Eye disorders: Eye irritation (burning, grittiness, itching, stinging and foreign body sensation); eye pain ; eyelash and vellus hair changes of the eyelid (increased length, thickness, pigmentation, and number of eyelashes)*; ocular hyperaemia (dilation and redness of the conjunctival vessels); iris hyperpigmentation (color changes in the eye area known as iris); blepharitis (inflammation of the eyelids); conjunctivitis* (inflammation or swelling of the conjunctiva – thin transparent layer that lines the inner surface of the eyelids and covers the white part of the eye); macular oedema including cystoid macular oedema* (build-up of fluid in the macula/centre of eye that causes it to swollen and distorts vision); photophobia* (discomfort or pain to the eyes due to light exposure or by presence of actual physical sensitivity of the eyes); eyelid oedema (swollen eyelids); keratitis* (inflammation of cornea); uveitis* (inflammation of middle layer of the eye or uvea); corneal oedema* (swelling of cornea); iritis* (inflammation that affects the colored ring around the eye's pupil); punctate keratitis* (eye disorder caused by death of small groups of cells on the surface of cornea); corneal erosion* (erosion or abrasion occurs when there is loss of the corneal's outer layer); trichiasis* (eyelashes grow inwards toward the eye); vision blurred*; periorbital and lid changes resulting in deepening of the eyelid sulcus*; darkening of the palpebral skin of the eyelids*; localized skin reaction on the eyelids*; iris cyst* (hollow cavities in the eye filled with secretion); pseudopemphigoid of ocular conjunctiva* (rare autoimmune disorders)
- Cardiac disorders: Angina (type of chest pain caused by reduced blood flow to the heart); palpitations* (noticeably rapid, strong or irregular heartbeats); angina unstable* (chest pain that is sudden and often gets worse over a short period of time)
- Respiratory, thoracic and mediastinal disorders: Asthma*; dyspnoea* (difficult breathing); asthma aggravation*; acute asthma attacks*
- Skin and subcutaneous tissue disorders: Rash; pruritus (severe itching)
- Musculoskeletal and connective tissue disorders: Myalgia* (muscle pain); arthralgia* (joint pain)
- General disorders and administration site conditions: Chest pain*

*ADR identified post-marketing

Adverse reactions reported with the use of eye drops containing phosphate buffers
Cases of corneal calcification have been reported very rarely in association with the use of phosphate-containing eye drops in some individual with significantly damaged corneas.

If any of the side effects gets serious, please tell your doctor or pharmacist.

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.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Optaprost
- *Storage*

Keep out of the reach and sight of children.

Before and after first opening:
Store below 30°C.

Protect from light.

Use this solution within 4 weeks 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*

The solution is a clear, colorless, sterile, aqueous ophthalmic solution buffered to approximately pH 6.5 to 6.9.

- *Ingredients*
- Active ingredient(s)
  Latanoprost 0.005% (50 mcg/ml)

- Inactive ingredients
  Sodium Chloride, Dibasic sodium phosphate hydrate, Sodium dihydrogen phosphate dehydrate, Polysorbate 80, Disodium edetate hydrate, Benzalkonium chloride concentrated solution 50, Hydrochloric Acid, Sodium hydroxide, Purified water.

- *MAL number:*

MAL19106009ACRZ

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Product Registration Holder
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