Avetaprost 0.005% w/v Eye Drop

Latanoprost 0.005% w/v

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What Avetaprost is used for

Avetaprost is used to treat conditions known as open angle glaucoma, chronic angle closure glaucoma and ocular hypertension.

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

How Avetaprost works

Avetaprost 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 Avetaprost

- When you must not use it

Avetaprost can be used in adult men and women (including the elderly). Efficacy and safety data in the age group <1 year are very limited. No data are available for preterm infants (less than 36 weeks gestational age).

Do not use Avetaprost if you are

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

- Before you start to use it

Talk to your doctor or the doctor treating your child or your pharmacist before you take Avetaprost 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 wear contact lenses.
- If you have suffered or are currently suffering from a viral infection of the eye caused by the herpes simplex virus (HSV)

- Taking other medicines

Avetaprost 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.

How to use Avetaprost

- How much to use

Recommended dosage for adults (including the elderly):

The dosage of Avetaprost 0.005% Eye Drop should not exceed once daily since it has been shown that more frequent administration decreases the intraocular pressure lowering effect.

If more than one topical ophthalmic drug is being used, the drugs should be administered at least five minutes apart.

Latanoprost eye drops may be used in paediatric patients at the same posology as in adults.

- When to use it

Recommended therapy is one eye drop in the affected eye(s) once daily. Optimal effect is obtained if Avetaprost 0.005% Eye Drop is administered in the evening.

Avetaprost 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. If you or your child wear contact lenses, they should be removed before using Avetaprost. After using Avetaprost you should wait 15 minutes before putting the contact lenses back in.

- How long to use it

Continue taking Avetaprost for as long as your doctor recommends.

- 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 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 Avetaprost accidentally.

While you are using it

- Things you must do

Use Avetaprost exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are using Avetaprost.

Tell your doctor immediately if you become pregnant while using this medication.

- Things you must not do

Do not give *Avetaprost* 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 Avetaprost 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.

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Side Effects
Like all medicines, Avetaprost can cause side effects, although not everybody gets them.
Very common effects (likely to affect more than 1 in 10 people):

- 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 Avetaprost 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 Avetaprost 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 (likely to affect less than 1 in 10 people):

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

Uncommon effects (likely to affect less than 1 in every 100 people):

- Eyelid swelling, dryness of the eye, inflammation or irritation of the surface of the eye (keratitis), blurred vision and conjunctivitis.
- Skin rash.

Rare effects (likely to affect less than 1 in every 1000 people):

- Inflammation of the iris, the coloured part of the eye (iritis/uveitis); swelling of the retina (macular oedema), symptoms of swelling or scratching/damage to the surface of the eye, swelling around the eye (periorbital oedema) misdirected eyelashes or an extra row of eyelashes.
- Skin reactions on the eyelids, darkening of the skin of the eyelids.
- Asthma, worsening of asthma and shortness of breath (dyspnoea).

Very rare effects (likely to affect less than 1 in 10,000 people):

- Worsening of angina in patients who also have heart disease. Chest pain.

Patients have also reported the following side-effects: fluid filled area within the coloured part of the eye (iris cyst), headache, dizziness, palpitations, muscle pain and joint 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 Avetaprost
Storage
Store in a refrigerator (2°C - 8°C). Protect from light.
After first opening the bottle: do not store above 25°C and use within four weeks.

Disposal
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required.

Product description
- *What it looks like*
Transparent and colorless ophthalmic solution contained in a transparent plastic container

- *Ingredients*
  - *Active ingredient:* Latanoprost.
  - *Inactive ingredients:* Dibasic sodium phosphate Anhydrous, Monobasic sodium phosphate (Monohydrate), Sodium chloride, Benzalkonium chloride and Sterile purified water.

- *MAL number*
MAL15025038ACZ

Manufacturer
Hanmi Pharmaceuticals Co., Ltd.
214, Muha-ro, Paltan-myeon,
Hwaseong-si, Gyeonggi-do,
South Korea.

Product Registration Holder
Apex pharmacy marketing Sdn Bhd
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