XALANOL® EYE DROPS

latanoprost (0.05mg/ml) & timolol maleate as timolol (5mg/ml)

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What *Xalanol Eye Drops* is used for

Xalanol Eye Drops is used for the treatment of open angle glaucoma or ocular hypertension. Both these conditions are linked with an increase in the pressure within the eyes, eventually affecting the eye sight.

How *Xalanol Eye Drops* works

Latanoprost works by reduction of elevated intraocular pressure within the eyes by increasing the natural out flow of fluid from inside the eye into the blood stream.

Timolol works by slowing the formation of fluid in the eye

Before you use *Xalanol Eye Drops*

-When you must not use it

Do not use *Xalanol Eye Drops,*

• If you are allergic to either Latanoprost, Timolol or any of the other ingredients in this medicine

• If you have difficulty in breathing because of lung disease or problem with your lungs.

• If you having any heart disease.

Pregnancy and lactation

Do not take *Xalanol Eye Drops* if you are pregnant, trying to get pregnant or think you may be pregnant.

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

- *Before you start to use it*

Talk to your doctor or pharmacist before using XALANOL 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
- Overactivity 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 *Xalanol Eye Drops* but follow the instructions for contact lens wearers (see How to use *Xalanol Eye Drops*)
- 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 *Xalanol Eye Drops* as timolol may change effects of some medicines used during anaesthesia.

- *Taking other medicines*

Tell your doctor if you are taking any other medicines (including eye drops), including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Especially if you are taking:

- Other prostaglandins, prostaglandin analogues or prostaglandin derivatives eyedrops (to reduce elevated intraocular pressure within the eyes in glaucoma)
- Calcium channel blockers (for coronary heart disease or for high blood pressure)
- Beta blockers (for high blood pressure)
- Antiarrhythmic (medications that normalize the heart rhythm)
- Digitalis glycosides (for heart failure)
- Parasympathomimetic (for the treatment of glaucoma)
- Guanethidine (for high blood pressure)
- Quinidine, fluoxetine, paroxetine (for depression)
- Adrenaline (to treat very serious allergic reactions)
- Clonidine (for high blood pressure)
- Anti-diabetics medicine (for diabetes)

How to use *Xalanol Eye Drops*

- *How much to use*

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- *Instruction for Xalanol Eye Drops use:*

- The usual dose for adult (including elderly) is one drop of *Xalanol Eye Drops* in the affected eye once a day.
- If you use any other eye drops you should wait at least 5 minutes after instilling *Xalanol Eye Drops.*
- Remove contact lenses before application of the *Xalanol Eye Drops.* Wait 15 minutes before you put your contact lens back in after using *Xalanol Eye Drops.*

- *For proper application of the Xalanol Eye Drops, following steps should be taken:*

1. Wash your hand before using.
2. Twist off the cap of the bottle.
3. Use your finger to gently pull down the lower eyelid of your affected eye.
4. Place the tip of container close to your eye taking care not to touch your eye.
5. Squeeze the container gently so that one drop goes into your eye, and 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 it in another eye if your doctor has told you to do so.
8. Put the cap back on the bottle

- *When to use it*

Use as directed by your doctor or pharmacist.

- *How long to use it*

Continue taking *Xalanol Eye Drops* for as long as your doctor 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)*

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.

If you put too many drops into your eyes this may cause irritation in the eyes or make your eye turn red.

If you accidently swallow *Xalanol Eye Drops*, contact your doctor as soon as possible

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 *Xalanol Eye Drops*.

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 *Xalanol Eye Drops* to anyone else, even if they have the same symptoms or condition as you.

- *Things to be careful of*

Driving and using machines

This medicine may affect your ability to drive or use machines. You may find that your vision is blurred with application of Xalanol Eye Drops in your eyes. Do not drive and operate machines until this wears off from your eyes. Contact your doctor or pharmacist if you are not sure.

Important information about your medicine

Xalanol Eye Drops contain benzalkonium chloride as preservative. This may lead to irritation in your eye. It is also known to discolor the soft contact lenses. Remove contact lenses prior to application and wait at least 15 minutes before putting them back in.

Side effects

Like all medicines, *Xalanol Eye Drops* 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.

The following side effects may occur with this medicine.

- *Very Common:*

- Due to the extended period of treatment, gradual change in eye color can occur due to increase in the amount of brown pigment in the colored part of eye known as iris.

Common:

- Eye pain
- Eye irritation
- Eye burning, eye itching, stinging and foreign body sensation.

- *Other side effect:*

The following side effects have been seen with *Xalanol Eye Drops:*

- Infections and Infestations: Developing a viral infection of the eye caused by the herpes simplex virus (HSV)
- Eye Disorders: Changes to the eyelashes and fine hairs around the eye, changes to the direction of eyelash growth, swelling around the eye, swelling of the colored part of the eye (iritis/uveitus), swelling at the back of the eye (macular oedema).
- Ear Disorders: Whistling/ringing in the ears (tinnitus)
- Heart Disorders: Worsening of angina, changes in heart rhythm, slowing of the heart, heart failure.
- Blood flow (Vascular)Disorders: Low blood pressure, discolouration/coldness of the fingers and toes (Raynaud's phenomenon) and coldness of the hands and feet.
- Breathing (Respiratory) Disorders: Asthma, worsening of asthma, shortness of breath, sudden difficulty to breathe (bronchospasm), cough.
- General Disorders: Chest pain, fatigue, swelling (oedema)

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 http://npra.moh.gov.my (Public → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Storage and Disposal of *Xalanol Eye Drops*

- *Storage*

  Keep out of the reach and sight of children.

  Xalanol Eye Drops should be stored in a refrigerator at a temperature of 2˚C - 8˚C. After opening of the bottle, it should be stored below 25˚C.

  Use *Xalanol Eye Drops* within 4 weeks after the opening of the bottles.

- *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*

  Colourless or pale yellow, clear solution.

- *Ingredients*

  - Active ingredient(s)

  latanoprost 0.05mg/ml & timolol maleate as timolol 5mg/ml

  - Inactive ingredients

  Sodium chloride, Sodium Dihydrogen Phosphate Monohyrdate, Disodium Hydrogen Phosphate Anhydrous, Benzalkonium Chloride, Water for Injection.

- *MAL number:*

  MAL**********

Manufacturer

Beximco Pharmaceuticals Ltd.
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Product Registration Holder

Vitamode (M) Sdn. Bhd.,
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