CONSUMER MEDICINE INFORMATION

Bimatoprost Actavis
Bimatoprost Eye Drops, Solution

What is in this leaflet

This leaflet answers some common questions about BIMATOPROST ACTAVIS. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using BIMATOPROST ACTAVIS against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What BIMATOPROST ACTAVIS is used for

BIMATOPROST ACTAVIS eye drops are used to lower raised pressure in the eye and to treat glaucoma.

Glaucoma is a condition in which the pressure of fluid in the eye may be high. However, some people with glaucoma may have normal eye pressure. Glaucoma is usually caused by a build up of the fluid which flows through the eye. This build up occurs because the fluid drains out of your eye more slowly than it is being pumped in. Since new fluid continues to enter the eye, joining the fluid already there, the pressure continues to rise.

This raised pressure may damage the back of the eye resulting in gradual loss of sight. Damage can progress so slowly that the person is not aware of this gradual loss of sight. Sometimes even normal eye pressure is associated with damage to the back of the eye.

There are usually no symptoms of glaucoma. The only way of knowing that you have glaucoma is to have your eye pressure, optic nerve and visual field checked by an eye specialist or optometrist. If glaucoma is not treated it can lead to serious problems, including total blindness. In fact, untreated glaucoma is one of the most common causes of blindness.

BIMATOPROST ACTAVIS eye drops lower the pressure in the eye by helping the flow of fluid out of the eye chamber.

BIMATOPROST ACTAVIS eye drops can be used alone or together with other eye drops/medicines to lower raised pressure within your eyes. Although BIMATOPROST ACTAVIS eye drops help control your condition, they will not cure it. BIMATOPROST ACTAVIS eye drops are only available with a doctor’s prescription from pharmacies. Your doctor may have prescribed BIMATOPROST ACTAVIS eye drops for another reason. Ask your doctor if you have any questions about why BIMATOPROST ACTAVIS eye drops have been prescribed for you.

For more information about glaucoma, contact Glaucoma New Zealand, Department of Ophthalmology, Private Bag 92019, Auckland, telephone 09 373 8779, email: info@glaucoma.org.nz
Before you use BIMATOPROST ACTAVIS

When you must not use it

Do not use BIMATOPROST ACTAVIS if:

- you have an allergy to bimatoprost or any of the ingredients listed at the end of this leaflet.
- the product does not look quite right such as discoloured.
- the bottle shows signs of tampering.
- the expiry date on the pack has passed. If you use this medicine after the expiry date has passed, it may not work effectively.

It is not known if BIMATOPROST ACTAVIS eye drops are safe and useful for children and adolescents under 18 years and therefore its use is not recommended.

These drops are for topical use only.

Before you start to use it

Tell your doctor if:

- you have had an allergy to any medicines or any other substances, such as foods, preservatives or dyes
- you have breathing problems
- you have liver or kidney problems
- you have low blood pressure or low heart rate
- you have a disease causing swelling of the back of the eye
- you have an inflammatory eye condition
- you are pregnant or intend to become pregnant. Like most medicines, BIMATOPROST ACTAVIS eye drops should not be used during pregnancy, unless clearly necessary.
- you are breast-feeding or intend to breast-feed.

Before you start using BIMATOPROST ACTAVIS eye drops your doctor should tell you that some changes to your eyes may occur which may be permanent.

Eyelashes may grow longer and thicker, and eyelashes, the skin around the eye and the coloured part of the eye may become darker.

If only one eye is being treated the cosmetic differences between the eyes may be noticeable. None of these changes affect vision. If you have any concerns, ask your doctor or pharmacist.

Taking other medicines

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

It is not expected that BIMATOPROST ACTAVIS will interact with other medicines, however you should always ask your optical practitioner, doctor or pharmacist if you have any concerns about using BIMATOPROST ACTAVIS eye drops as well as other medications.

How to use BIMATOPROST ACTAVIS

How much to use

Your doctor will tell you how many drops you need to use each day.

Use BIMATOPROST ACTAVIS eye drops only as prescribed by your doctor.
The usual dose of BIMATOPROST ACTAVIS eye drops is one drop in the affected eye(s) once daily, given in the evening.

Follow all directions given to you by your doctor carefully. The directions may differ from the information contained in this leaflet.

Use BIMATOPROST ACTAVIS eye drops every day, at about the same time each day, unless your doctor tells you otherwise. Using your eye drops at the same time each day will have the best effect on your eye pressure. It will also help you remember when to use the eye drops.

If you are using more than one eye drop product, wait 5 minutes before using the second product.

If you are being changed from one eye drop to another, follow your doctor's instructions carefully as to when to stop the old drops and when to start the new drops.

**How to use it**

You may find it easier to put drops in your eye while you are sitting or lying down.

1. Wash your hands well with soap and water.
2. Be careful not to touch the dropper tip against your eye, eyelid or anything else to avoid contaminating the eye drops. Contaminated eye drops may give you an eye infection.
3. If you wear soft contact lenses, they should be removed before using the eye drops and wait at least 15 minutes before reinserting.
4. BIMATOPROST ACTAVIS is supplied in a plastic bottle with a plastic screw cap. When using the bottle for the first time, twist the cap open to break the seal.
5. Tilt your head back and look at the ceiling.
6. Pull the lower eyelid downwards to form a pocket.
7. Hold the bottle upside down above the eye and gently squeeze the bottle to release a drop into your eye.
8. Close your eye and keep it closed. While your eye is still closed, place your index finger against the inside corner of your eye and press against your nose for about two minutes. This will help to stop the medicine from draining through the tear duct to the nose and throat, from where it can be absorbed into other parts of your body. Ask your doctor for more specific instructions on this technique. Do not blink or rub your eye.
9. Repeat for the other eye if necessary.
10. Recap the bottle after every use.
11. Wash your hands again with soap and water to remove any residue.

Store the bottle in a cool place where the temperature stays below 25°C.

Discard any remaining solution 28 days after opening the bottle.

**How long to use it**

BIMATOPROST ACTAVIS eye drops help control your condition, but do not cure it. Therefore, BIMATOPROST ACTAVIS eye drops must be used every day.
Continue using BIMATOPROST ACTAVIS eye drops for as long as your doctor prescribes.

**If you forget to use it**

If it is almost time for your next dose, skip the dose you missed and use your next dose when you are meant to. Otherwise, use the drops as soon as you remember, and then go back to using them as you would normally.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

Do not use double the amount to make up for the dose that you missed.

**If you use too much (overdose)**

If you accidentally put several drops in your eye(s), immediately rinse your eye(s) with warm water.

If you think that you or anyone else may have swallowed any or all of the contents of a bottle of BIMATOPROST ACTAVIS eye drops, immediately telephone your doctor or National Poisons Information Centre (telephone 0800 POISON or 0800 764 766) for advice, or go to accident and emergency at your nearest hospital. Do this even if there are no signs of discomfort or poisoning.

**While you are using BIMATOPROST ACTAVIS**

**Things you must do**

Have your eye pressure checked when your eye specialist says, to make sure BIMATOPROST ACTAVIS is working.

If you develop an eye infection, receive an eye injury, or have eye surgery tell your doctor.

If you become pregnant while using BIMATOPROST ACTAVIS tell your doctor immediately.

Tell your doctor if your condition gets worse or does not get better while using BIMATOPROST ACTAVIS.

If you are about to start any new medicine tell your doctor and pharmacist that you are using BIMATOPROST ACTAVIS.

**Things you must not do**

Do not give BIMATOPROST ACTAVIS to anyone else, even if they have the same condition as you.

Do not stop using BIMATOPROST ACTAVIS without first talking to your doctor. If you stop using your eye drops, your eye pressure may rise again and damage to your eye may occur.

**Things to be careful of**

Your vision may blur for a short time after you put in your BIMATOPROST ACTAVIS eye drops. If this happens you should wait until you can see well again before you drive or use machinery.

BIMATOPROST ACTAVIS eye drops are not expected to cause any problems with your ability to drive a car or operate machinery. However, as a general precaution be careful driving or operating machinery until you know how BIMATOPROST ACTAVIS eye drops affect you.
Adverse Effects

Tell your optical practitioner, doctor or pharmacist as soon as possible if you do not feel well while you are using BIMATOPROST ACTAVIS.

Check with your doctor as soon as possible if you have any problems while using BIMATOPROST ACTAVIS, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Ask your optical practitioner, doctor or pharmacist any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- red, congested eyes
- itching of eye/s
- small lesions or erosions on the eye surface
- feeling of something in the eye
- dryness of the eye
- growth of eyelashes
- pain in the eye
- irritation of the eye
- inflamed/red eyelid/s
- darkening of skin around eye.

Less often the following effects have been seen:

- discharge from the eye
- eye discomfort
- inflamed areas around the eye/s
- swelling of the conjunctiva
- discharge from the eye
- eyelash darkening
- eyelid itchiness and redness
- darkening of the coloured part of the eye
- burning of the eye and nearby eyelid
- sensitivity to light
- tears
- changes in/disturbance of vision.

Rarely other eye related problems can occur such as spasm of the eye where there is uncontrolled blinking, eyelid retraction, inflammation of the coloured part of eye, bleeding in eye chamber, deepened eyelids, redness and inflammation on the eye and surrounding eye area, eyelid swelling, swelling of the back of the eye.

There can also be effects on the body as a whole such as nausea, weakness, infection, headache and very rarely depression, sensation of spinning in stable surroundings, dizziness, excessive growth of hair, abnormal hair growth, asthma, exacerbation of asthma, shortness of breath and high blood pressure.

After using BIMATOPROST ACTAVIS

Storage

Keep your eye drops in a cool place where the temperature stays below 25°C.
Do not store it or any other medicine in the bathroom or near a sink. Do not leave it in the car or on window sills. Do not carry the eye drops in pockets of your clothes. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Do not leave the cap off the bottle for any length of time to avoid contaminating the eye drops.

**Disposal**

Write the date on the bottle when you open the eye drops and throw out any remaining solution after 28 days.

Eye drops contain a preservative which helps prevent germs growing in the solution for the first 28 days after opening the bottle. After this time there is a greater risk that the drops may become contaminated and cause an eye infection. A new bottle should be opened.

If your doctor tells you to stop using the eye drops or they have passed their expiry date, ask your pharmacist what to do with any remaining solution.

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**Product description**

**What BIMATOPROST ACTAVIS looks like**

BIMATOPROST ACTAVIS eye drops are a clear, colourless solution in a plastic dropper bottle with a plastic screw cap.

**Ingredients**

BIMATOPROST ACTAVIS contains the active ingredient bimatoprost. Each mL contains bimatoprost 0.03%w/v equivalent to 300 micrograms per mL.

It also contains sodium chloride, sodium phosphate dibasic heptahydrate, citric acid monohydrate, water for injection and benzalkonium chloride as a preservative. Small amounts of sodium hydroxide and/or hydrochloric acid may be added to adjust pH.

**Supplier**

BIMATOPROST ACTAVIS is distributed in New Zealand by:

Teva Pharma (New Zealand) Limited  
PO Box 128 244  
Remuera  
Auckland 1541  
Telephone: 0800 800 097

**Date of preparation**

4 May 2017