

Package leaflet: Information for the user

[Invented name] 0.3 mg/mL + 5 mg/mL eye drops, solution bimatoprost/timolol

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What [Invented name] is and what it is used for
2. What you need to know before you use [Invented name]
3. How to use [Invented name]
4. Possible side effects
5. How to store [Invented name]
6. Contents of the pack and other information

1. What [Invented name] is and what it is used for

[Invented name] contains two different active substances (bimatoprost and timolol) that both reduce pressure in the eye. Bimatoprost belongs to a group of medicines called prostamides, a prostaglandin analogue. Timolol belongs to a group of medicines called beta-blockers.

Your eye contains a clear, watery liquid that feeds the inside of the eye. Liquid is constantly being drained out of the eye and new liquid is made to replace this. If the liquid cannot drain out quickly enough, the pressure inside the eye builds up and could eventually damage your sight (an illness called glaucoma). [Invented name] works by reducing the production of liquid and also increasing the amount of liquid that is drained. This reduces the pressure inside the eye.

[Invented name] eye drops are used to treat high pressure in the eye in adults, including the elderly. This high pressure can lead to glaucoma. Your doctor will prescribe you [Invented name] when other eye drops containing beta-blockers or prostaglandin analogues have not worked sufficiently on their own.

[Invented name] eye drops solution is a sterile solution that does not contain a preservative.

2. What you need to know before you use [Invented name]

Do not use [Invented name]

- if you are allergic to bimatoprost, timolol, beta-blockers or any of the other ingredients of this medicine (listed in section 6).
- if you have now or have had in past respiratory problems such as asthma, severe chronic obstructive bronchitis (severe lung disease which may cause wheeziness, difficulty in breathing and/ or long-standing cough)
- if you have heart problems such as low heart rate, heart block, or heart failure

Warnings and precautions

Talk to your doctor before using [Invented name] 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,

- disturbances of heart rate such as slow heart beat
- breathing problems, asthma or chronic obstructive pulmonary disease
- poor blood circulation disease (such as Raynaud's disease or Raynaud's syndrome)
- overactivity of the thyroid gland as timolol may mask signs and symptoms of thyroid disease
- diabetes as timolol may mask signs and symptoms of low blood sugar
- severe allergic reactions
- liver or kidney problems
- eye surface problems
- separation of one of the layers within the eyeball after surgery to reduce the pressure in the eye
- known risk factors for macular oedema (swelling of the retina within the eye leading to worsening vision), for example, cataract surgery

Tell your doctor before surgical anaesthesia that you are using [Invented name] as timolol may change effects of some medicines used during anaesthesia.

[Invented name] may cause your eyelashes to darken and grow, and cause the skin around the eyelid to darken too. The colour of your iris may also go darker over time. These changes may be permanent. The change may be more noticeable if you are only treating one eye.

Children and adolescents

[Invented name] should not be used in children and teenagers under 18.

Other medicines and [Invented name]

[Invented name] can affect or be affected by other medicines you are using, including other eye drops for the treatment of glaucoma. Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Tell your doctor if you are using or intend to use:

- medicines to lower blood pressure
- heart medicine
- medicines to treat diabetes
- quinidine (used to treat heart conditions and some types of malaria)
- medicines to treat depression known as fluoxetine and paroxetine

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Do not use [Invented name] if you are pregnant unless your doctor still recommends it.

Do not use [Invented name] if you are breast-feeding. Timolol may get into your breast milk. Ask your doctor for advice before taking any medicine during breast-feeding.

Driving and using machines

[Invented name] may cause blurred vision in some patients. Do not drive or use machines until the symptoms have cleared.

3. How to use [Invented name]

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is one drop once a day, either in the morning or in the evening in each eye that needs treatment. Use at the same time each day.

Do not allow the tip of the multi dose container to touch the eye or areas around the eye. It could cause injury to your eye. The eye drops solution may become contaminated with bacteria that can cause eye infections leading to serious damage of the eye, even loss of vision.

To avoid possible contamination of the multi-dose container, keep the tip of the multi-dose container away from contact with any surface.

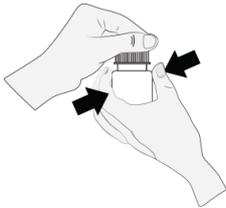
Instructions for use

Before instillation of the eye drops:

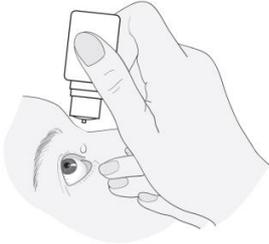
- Wash your hands before opening the bottle.
- Do not use this medicine if you notice that the tamper-proof seal on the bottle neck is broken before you first use it.
- When using for the first time, before delivering a drop to the eye, you should first of all practise using the dropper bottle by squeezing it slowly to deliver one drop into the air, away from the eye.
- When you are confident that you can deliver one drop at a time, choose the position that you find most comfortable for the instillation of the drops (you can sit down, lie on your back, or stand in front of a mirror).

Instillation:

1. Hold the bottle directly below the cap and turn the cap to open the bottle. Do not touch anything with the tip of the bottle to avoid contamination of the solution.



2. Tilt your head backwards and hold the bottle above your eye.



3. Pull the lower eyelid down and look up. Squeeze the bottle gently in the middle and let a drop fall into your eye. Please note that there might be a few seconds delay between squeezing and the drop coming out. Do not squeeze too hard.

If a drop misses your eye, try again.

If you are not sure how to administer your medicine, ask your doctor, pharmacist or nurse.



4. Blink a few times so that the drop spreads over the eye.

5. Repeat the instructions 2. – 4. to deliver a drop into the other eye also, if your doctor has instructed you to do this. Sometimes only one eye needs to be treated and your doctor will advise if this applies to you and which eye needs treatment.



6. After use and prior to recapping, the bottle should be shaken once in a downwards direction, without touching the dropper tip, in order to remove any residual liquid on the tip. This is necessary in order to ensure delivery of subsequent drops.

7. After you have used all doses there will be some [Invented name] left in the bottle. You should not be concerned since an extra amount of [Invented name] has been added and you will get the full amount of [Invented name] that your doctor has prescribed. Do not attempt to use the excess medicine remaining in the bottle after you have completed the course of treatment.

Do not use the eye drops for longer than 28 days after first opening the bottle.

If you use [Invented name] with another eye medicine, leave at least 5 minutes between putting in [Invented name] and the other medicine. Use any eye ointment or eye gel last.

If you use more [Invented name] than you should

If you use more [Invented name] than you should, it is unlikely to cause you any serious harm. Put your next dose in at the usual time. If you are worried, talk to your doctor or pharmacist.

If you forget to use [Invented name]

If you forget to use [Invented name], use a single drop as soon as you remember, and then go back to your regular routine. Do not use a double dose to make up for a forgotten dose.

If you stop using [Invented name]

[Invented name] should be used every day to work properly.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

You can usually carry on taking the drops, unless the effects are serious. If you're worried, talk to a doctor or pharmacist. Do not stop using [Invented name] without speaking to your doctor.

The following eye side effects may be seen with bimatoprost/timolol:

Very common (may affect more than 1 in 10 people):

- eye redness

Common (may affect up to 1 in 10 people):

- burning, itching, stinging
- sensitivity to light
- eye pain
- sticky eyes
- dry eyes
- a feeling of something in the eye

- small breaks in the surface of the eye with or without inflammation
- difficulty in seeing clearly
- redness and itching of the eyelids
- darkening of the eyelids, darker skin colour around the eyes
- headache
- longer eyelashes
- eye irritation
- watery eyes
- swollen eyelids
- reduced vision
- runny nose
- hair growing around the eye
- dizziness

Uncommon (may affect up to 1 in 100 people):

- iris inflammation
- swollen conjunctiva (see-through layer of the eye)
- painful eyelids
- tired eyes
- in-growing eyelashes
- darker iris colour
- eyes appear sunken
- eyelid has moved away from the surface of the eye
- shortness of breath

Not known (frequency cannot be estimated from available data):

- cystoid macular oedema (swelling of the retina within the eye leading to worsening vision)
- difficulty breathing / wheezing

Additional side effects have been seen in patients using eye drops containing bimatoprost and so may possibly be seen with [Invented name]:

- allergic reaction in the eye, darkening of the eyelashes, darkening of the iris colour, increased blinking, bleeding in the back of the eye (retinal bleeding), inflammation within the eye
- high blood pressure
- weakness
- an increase in blood test results that show how your liver is working

Additional side effects have been seen in patients using eye drops containing timolol and so may possibly be seen with [Invented name]. Like other medicines applied into eyes, timolol is absorbed into the blood. This may cause similar side effects as seen with “intravenous” and /or “oral” beta-blocking agents. The chance of having side effects after using eye drops is lower than when medicines are for example, taken by mouth or injected. Listed side effects include reactions seen within the class of beta-blockers when used for treating eye conditions:

- severe allergic reactions with swelling and difficulty breathing which could be life-threatening; allergic reactions (including rash, itching, hives);
- low blood sugar
- difficulty sleeping, nightmares, depression; memory loss
- fainting; stroke; decreased blood flow to the brain; worsening of myasthenia gravis (increased muscle weakness); tingling sensation; dizziness
- decreased sensation of your eye surface; double vision; drooping eyelid; separation of one of the layers within the eyeball after surgery to reduce the pressure in the eye; inflammation of the surface of the eye; blurred vision
- heart failure; irregularity or stopping of the heartbeat; slowing of heart rate; slow or fast heartbeat; too much fluid, mainly water, accumulating in the body; chest pain
- low blood pressure; swelling or coldness of your hands, feet and extremities, caused by constriction of your blood vessels

- cough
- diarrhoea; stomach pain; feeling and being sick; changes in your taste sensation; indigestion; dry mouth
- red scaly patches on skin; skin rash; hair loss
- muscle pain
- reduced sexual urge; sexual dysfunction
- tiredness

Other side effects reported with eye drops containing phosphates

In very rare cases, some patients with severe damage to the clear layer at the front of the eye (the cornea) have developed cloudy patches on the cornea due to calcium build-up during treatment.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system <to be completed nationally>](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [Invented name]

Keep this medicine out of the sight and reach of children.

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

After first opening, the product may be stored for a maximum of 28 days. No special storage conditions are required.

Do not use this medicine if you notice that the seal is broken the first time you use the container.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What [Invented name] contains

- The active substances are bimatoprost 0.3 mg/mL and timolol 5 mg/mL corresponding to timolol maleate 6.83 mg/mL.
- The other ingredients are sodium chloride, disodium hydrogen phosphate heptahydrate, citric acid monohydrate, sodium hydroxide or/and hydrochloric acid (for pH adjustment) and water for injections.

What [Invented name] looks like and contents of the pack

[Invented name] is presented as a clear, colorless aqueous solution filled in a white opaque 5 ml LDPE bottle and white Novelia nozzle (HDPE and silicone) with a blue tip and sealed with a white HDPE cap and packed in cardboard box.

The following pack sizes are available: cartons containing 1 or 3 bottles

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

<[To be completed nationally]>

This leaflet was last revised in