

Package leaflet: Information for the user

Bimtim 0.3 mg/ml + 5 mg/ml eye drops, solution, single-dose container 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.

This medicine 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 and/or severe chronic obstructive pulmonary disease (lung disease which may cause wheeziness, difficulty in breathing and/ or long-standing cough) or other types of breathing problems
- if you have heart problems such as low heart rate, heart block, or heart failure

Warnings and precautions

Before you use this medicine, tell your doctor 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 reaction
- 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.

During treatment, [Invented name] may cause a loss of fat around the eye, which may cause your eyelid crease to deepen, your eye to appear sunken (enophthalmos), your upper eyelid to droop (ptosis), the skin around your eye to tighten (involution of dermatochalasis) and the lower white part of your eye to become more visible (inferior scleral show). The changes are typically mild, but if pronounced, they can affect your field of vision. The changes may disappear if you stop taking [Invented name].

[Invented name] may also 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. These changes may be permanent. The changes may be more noticeable if you are only treating one eye.

[Invented name] may cause hair growth when in contact with the skin surface.

This medicine contains 0.38 mg phosphates in each 0.4 ml of solution which is equivalent to 0.96 mg/ml.

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. Please 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) or 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.

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]

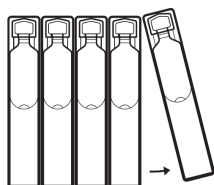
Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual 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.

Instructions for use

Wash your hands before use. Make sure that the single-dose container is intact before use. The solution should be used immediately after opening. To avoid contamination, do not let the open-end of the single-dose container touch your eye or anything else.

1. Tear 1 single-dose container from the strip.



2. Hold the single-dose container upright (with the cap pointing upwards) and twist off the cap.



3. Gently pull down the lower eyelid to form a pocket. Turn the single-dose container upside down and squeeze it to release 1 drop into the affected eye(s).



4. Whilst keeping the eye closed, press your finger against the corner of the closed eye (the site where the eye meets the nose) and hold for 2 minutes. This helps to stop [Invented name] getting into the rest of the body.



5. Throw away the single-dose container after you have used it, even if there is some solution left.

If a drop misses your eye, try again. Wipe off any excess that runs down the cheek.

If you wear contact lenses, take your lenses out before using this medicine. Wait 15 minutes after using the drops, and before you put your lenses back in.

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 side effects may be seen with [Invented name]:

Very common: may affect more than 1 in 10 people

Affecting the eye

- redness
- loss of fat in the eye region which can lead to deepening of your eyelid crease, sunken eye (enophthalmos), drooping eyelid (ptosis), tightening of the skin around your eye (involution of dermatochalasis), and the lower white part of your eye to become more visible (inferior scleral show)

Common: may affect up to 1 in 10 people

Affecting the eye

- burning
- itching
- stinging
- irritation of the conjunctiva (see-through layer of the eye)
- 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
- hair growing around the eye
- darkening of the eyelids
- darker skin colour around the eyes
- longer eyelashes

- eye irritation
- watery eyes
- swollen eyelids
- reduced vision

Affecting other parts of the body

- runny nose
- headache

Uncommon: may affect up to 1 in 100 people

Affecting the eye

- abnormal sensation in the eye
- iris inflammation
- swollen conjunctiva (see-through layer of the eye)
- painful eyelids
- tired eyes
- in-growing eyelashes
- darkening of iris colour
- eyelid shrinking, moving away from surface of the eye leading to incomplete closure of the eyelids)
- skin tightness of the eyelids
- darkening of eyelashes

Affecting other parts of the body

- shortness of breath

Not known: frequency cannot be estimated from the available data

Affecting the eye

- cystoid macular oedema (swelling of the retina within the eye leading to worsening vision)
- eye swelling
- blurred vision
- ocular discomfort

Affecting other parts of the body

- difficulty breathing/wheezing
- symptoms of allergic reaction (swelling, redness of the eye and rash of the skin)
- changes in your taste sensation
- dizziness
- slowing of heart rate
- high blood pressure
- difficulty sleeping
- nightmare
- asthma
- hair loss
- skin discolouration (periocular)
- tiredness

Additional side effects have been seen in patients using eye drops containing timolol or bimatoprost 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 bimatoprost and timolol when used for treating eye conditions:

- severe allergic reactions with swelling and difficulty breathing which could be life-threatening
- low blood sugar
- depression; memory loss; hallucination
- fainting; stroke; decreased blood flow to the brain; worsening of myasthenia gravis (increased muscle weakness); tingling sensation
- 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, bleeding in the back of the eye (retinal bleeding), inflammation within the eye, increased blinking
- heart failure; irregularity or stopping of the heartbeat; 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, worsening of asthma, worsening of the lung disease called chronic obstructive pulmonary disease (COPD)
- diarrhoea; stomach pain; feeling and being sick; indigestion; dry mouth
- red scaly patches on skin; skin rash
- muscle pain
- reduced sexual urge; sexual dysfunction
- weakness
- an increase in blood test results that show how your liver is working

Other side effects reported with eye drops containing phosphates

This medicine contains 0.38 mg phosphates in each 0.4 ml of solution which is equivalent to 0.96 mg/ml. If you suffer from severe damage to the clear layer at the front of the eye (the cornea), phosphates may cause in very rare cases 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 listed in Appendix V](#).^{*} 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 single dose container and the carton. The expiry date refers to the last day of that month.

This medicine is for single use only and does not contain preservatives. Do not keep any unused solution.

This medicinal product does not require any special temperature storage conditions.

Keep the single-dose containers in the pouch and outer carton. Use within 7 days after the opening of the pouch

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 6.8 mg/ml.
- The other ingredients are sodium chloride, sodium phosphate dibasic heptahydrate, citric acid monohydrate and water for injection. Small amounts of hydrochloric acid or sodium hydroxide may be added to bring the solution to the correct pH (acidity) level.

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

[Invented name] is a clear and colourless solution supplied in single-dose plastic containers, each containing 0.4 ml of solution.

Packs contain 6 or 18 PET/AL/PE pouches, each pouch containing 5 single-dose containers, for a total of 30 or 90 single-dose containers in a carton, respectively.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

EQL Pharma AB
Stortorget 1
222 23 Lund
Sweden

Manufacturer

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