

Package leaflet: Information for the patient**Bimatoprost Timolol
0.3mg/ml + 5mg/ml eye drops,
solution, in single-dose container**

Bimatoprost/Timolol

The name of your medicine is Bimatoprost/Timolol 0.3mg/ml +5mg/ml eye drops, solution, in single dose container, however it will be referred to as Bimatoprost/Timolol single dose throughout this leaflet.

Read all of this leaflet carefully before you start taking 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.

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1. What Bimatoprost/Timolol single-dose is and what it is used for

Bimatoprost/Timolol single-dose 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). Bimatoprost/Timolol single-dose works by reducing the production of liquid and also increasing the amount of liquid that is drained. This reduces the pressure inside the eye.

Bimatoprost/Timolol single-dose 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 Bimatoprost/Timolol single-dose 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 Bimatoprost/Timolol single-dose**Do not use this medicine:**

- if you are allergic to bimatoprost, timolol, beta-blockers or any of the other ingredients of Bimatoprost/Timolol single-dose (listed in section 6).
- if you have now or have had in the 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

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 heartbeat
- 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 Bimatoprost/Timolol single-dose as timolol may change the effects of some medicines used during anaesthesia.

During treatment, Bimatoprost/Timolol single-dose 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 Bimatoprost/Timolol single-dose. This medicine 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 change may be more noticeable if you are only treating one eye. This medicine may cause hair growth when in contact with the skin surface.

Children and adolescents

This medicine should not be used in children and teenagers under 18.

Other medicines and Bimatoprost/Timolol single-dose

Bimatoprost/Timolol single-dose 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 this medicine if you are pregnant unless your doctor still recommends it.

Do not use this medicine 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

This medicine may cause blurred vision in some patients. Do not drive or use machines until the symptoms have cleared.

3. How to take Bimatoprost/Timolol single-dose

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.

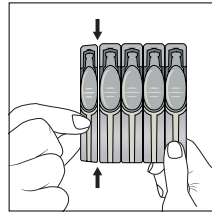
Do not use more than once a day as the effectiveness of treatment may be reduced.

Do not allow the single-dose container to touch the eye or areas around the eye. It could cause injury to your eye. It may also 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 single-dose container, wash your hands before using this medicine and keep the tip of the single-dose container away from contact with any surface. A new single-dose container should be opened immediately prior to each use; there is enough solution in each container for both eyes if your doctor has told you to use the drops in both eyes.

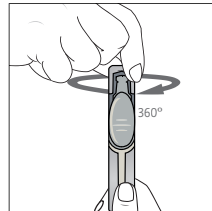
Instructions for Use:

Open the sachet which contains a strip of 5 individual single-dose containers.

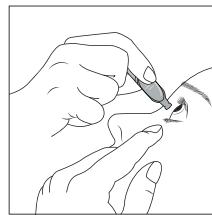
1. Wash your hands.
2. Take the strip of containers from the sachet.
3. Detach one single-dose container from the strip.



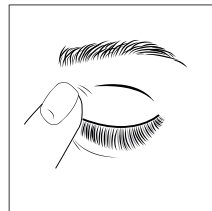
4. Put the remaining strip back in the sachet and fold the edge to close the sachet.
5. To open the container, twist off the tab. Continue twisting until the lid detaches. **Do not pull** the lid to remove.



6. Hold the container between your thumb and index finger.
7. Check for any sharp edges or burrs around the container opening before administering a drop.
8. Tilt your head backwards or lie down. Look up and pull the lower eyelid downwards with the other hand. Do not allow any part of the container to touch your eye or any area around your eye. Gently squeeze the container to let one drop fall into the space between the lid and the eye. Do not blink while applying the drop to your eye. Each single-dose container contains enough solution for both eyes.



9. Close your eye and press the inner corner of the eye with your finger for about two minutes. This helps to stop the medicine from getting into the rest of the body.



10. Wipe off any excess solution from the skin around the eye.

If your doctor has told you to use drops in both eyes, repeat steps 7 to 10 for your other eye. After putting the drop into the eye(s), throw away the used single-dose container even if there is solution remaining to avoid contamination of the preservative free solution.

Store the remaining containers in the sachet; the remaining containers must be used within 7 days after opening of the sachet. If there are any containers left 7 days after opening the sachet they should be safely thrown away and a fresh sachet opened. It is important to continue to use the eye drops as prescribed by your doctor.

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

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 Bimatoprost/Timolol single-dose with another eye medicine, leave at least 5 minutes between putting in Bimatoprost/Timolol single-dose and the other medicine. Use any eye ointment or eye gel last.

If you use more Bimatoprost/Timolol single-dose than you should

If you use more of this medicine 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 Bimatoprost/Timolol single-dose

If you forget to use this medicine, 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 Bimatoprost/Timolol single-dose

This medicine 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 using the drops, unless the effects are serious. If you're worried, talk to your doctor or pharmacist. Do not stop using Bimatoprost/Timolol single-dose without speaking to your doctor.

The following side effects may be seen with Bimatoprost/Timolol:

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

Affecting the eye

redness.

Affecting the eye region

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 side effects (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 side effects (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, eyes appear sunken, eyelid drooping, eyelid shrinking (moving away from the 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 Bimatoprost/Timolol single-dose. 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 0.38mg phosphates in each 0.4ml of solution which is equivalent to 0.95mg/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 Yellow Card Scheme (website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Bimatoprost/Timolol single-dose

Keep 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 sachet and place the sachet back in the carton in order to protect from light and moisture.

Once the sachet is opened, use the single-dose containers within 7 days. Discard the opened single-dose container immediately after use.

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 to protect the environment.

6. Contents of the pack and other information

What Bimatoprost/Timolol single-dose contains

- The active substances are bimatoprost 0.3mg/ml and timolol 5mg/ml corresponding to timolol maleate 6.8mg/ml.
- The other ingredients are: sodium chloride, sodium phosphate dibasic heptahydrate, citric acid monohydrate and water for injections. Small amounts of hydrochloric acid or sodium hydroxide may be added to bring the solution to the correct pH (acidity) level.

What Bimatoprost/Timolol single-dose looks like and contents of the pack

Bimatoprost/Timolol single-dose is a colourless to slightly yellow solution supplied in single-dose plastic (LDPE) containers, each containing 0.4ml of solution.

Pack contains 1, 6 or 18 foil sachets each containing 5 single-dose containers, for a total of 5, 30 or 90 single-dose containers in a carton, respectively.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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This leaflet was last revised in 05/2023.

1010532-P4.3XXXXXXXX-XX