

If a drop misses your eye, try again.
To avoid contamination, do not let the tip of the bottle touch your eye or anything else. Put the cap back on and close the bottle straight after you have used it.
If you use Bimatoprost/Timolol with another eye medicine, leave at least 5 minutes between putting in Bimatoprost/Timolol and the other medicine. Use any eye ointment or eye gel last.
If you use more Bimatoprost/Timolol than you should
If you use more Bimatoprost/Timolol 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
If you forget to use Bimatoprost/Timolol, 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
Bimatoprost/Timolol should be used every day to work properly.
Do not stop using Bimatoprost/Timolol without speaking to your doctor. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

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 Bimatoprost/Timolol without speaking to your doctor. The following side effects may be seen with Bimatoprost/Timolol.

Very common side effects (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 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
- eyelid has moved away from the surface of the eye
- darkening of eyelashes.

Affecting other parts of the body:

- Shortness of breath.

Side effects where the frequency is 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)
- skin discolouration (periocular)
- changes in your taste sensation
- dizziness
- slowing of heart rate
- high blood pressure
- difficulty sleeping
- nightmares
- asthma
- hair loss
- 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. Like other medicines applied into eyes, timolol is absorbed into the blood. This may cause similar side effects as seen with "systemic" 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 with 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;
- 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;
- hallucinations.

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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or www.nps.gov.uk. You can help provide more information on the safety of this medicine.

5. How to store Bimatoprost/Timolol

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. This medicine does not require any special storage conditions. Once opened, solutions may become contaminated, which can cause eye infections. Therefore, you must throw away the bottle 4 weeks after you first opened it, even if some solution is left. To help you remember, write down the date that you opened it in the space on the carton. 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 Bimatoprost/Timolol contains:

- The active substances are bimatoprost 0.3 mg/ml and timolol 5 mg/ml corresponding to timolol malesin 6.8 mg/ml.
- The other ingredients are benzalkonium chloride (a preservative), disodium phosphate heptahydrate, sodium chloride, citric acid monohydrate and purified water. Small amounts of hydrochloric acid or sodium hydroxide may be added to bring the solution to the correct pH (acidity) level (see section 2, "Bimatoprost/Timolol contains phosphates and benzalkonium chloride").

What Bimatoprost/Timolol looks like and contents of the pack

Bimatoprost/Timolol is a practically clear, colourless to slightly yellow solution in a plastic bottle. Each pack contains either 1 plastic bottle or 3 plastic bottles each with a screw cap. Each bottle is about half full and contains 5 millilitres of solution. This is enough for 4 weeks' usage. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Mylan, Potters Bar, EN6 1TL, United Kingdom

Manufacturer

Rompapharm Company S.R.L., I.A. Sirolo Street Otopeni, Ilfov 075100, Romania

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