Package leaflet: Information for the user

Bimatoprost/Timolol Rompharm 0.3 mg/ml + 5 mg/ml oogdruppels, oplossing
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, please ask your doctor or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Bimatoprost/Timolol Rompharm is and what it is used for

Bimatoprost/Timolol Rompharm 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 Rompharm 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 Rompharm 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 Rompharm when other eye drops containing beta-blockers or prostaglandin analogues have not worked sufficiently on their own.

2. What you need to know before you use Bimatoprost/Timolol Rompharm

Do not use Bimatoprost/Timolol Rompharm eye drops, solution
- if you are allergic to bimatoprost, timolol, beta-blockers or any of the other ingredients of Bimatoprost/Timolol Rompharm (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
Talk to your doctor or pharmacist before you use Bimatoprost/Timolol Rompharm, 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 Rompharm as timolol may change effects of some medicines used during anaesthesia.
During treatment, Bimatoprost/Timolol Rompharm 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 Rompharm. Bimatoprost/Timolol Rompharm 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. Bimatoprost/Timolol Rompharm may cause hair growth when in contact with the skin surface.

Children and adolescents
Bimatoprost/Timolol Rompharm should not be used in children and teenagers under 18.

Other medicines and Bimatoprost/Timolol Rompharm
Bimatoprost/Timolol Rompharm 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 Bimatoprost/Timolol Rompharm if you are pregnant unless your doctor still recommends it.
Do not use Bimatoprost/Timolol Rompharm 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
Bimatoprost/Timolol Rompharm may cause blurred vision in some patients. Do not drive or use machines until the symptoms have cleared.

Bimatoprost/Timolol Rompharm contains Benzalkonium chloride
Bimatoprost/Timolol Rompharm contains a preservative called benzalkonium chloride.
This medicine contains 0.15 mg benzalkonium chloride in each 3 ml of solution which is equivalent to 0.05 mg/ml.
Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. You should remove contact lenses before using this medicine and put them back 15 minutes afterwards.
Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or disorders of the cornea (the clear layer at the front of the eye). If you feel abnormal eye sensation, stinging or pain in the eye after using this medicine, talk to your doctor.

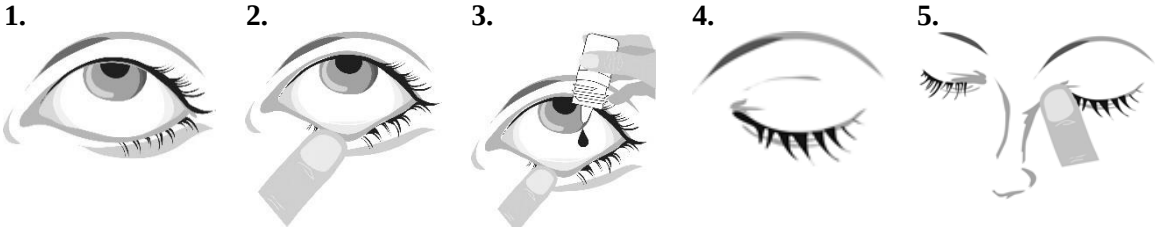
Bimatoprost/Timolol Rompharm contains phosphates

Bimatoprost/Timolol Rompharm contains 0.95 mg phosphates in each 1 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.

3. How to use Bimatoprost/Timolol Rompharm

Always use Bimatoprost/Timolol Rompharm 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
You must not use the bottle if the tamper-proof seal on the bottle neck is broken before you first use it.



1. Wash your hands. Tilt your head back and look at the ceiling.
2. Gently pull down the lower eyelid until there is a small pocket.
3. Turn the bottle upside down and squeeze it to release one drop into each eye that needs treatment.
4. Let go of the lower lid, and close your eye.
5. 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 Bimatoprost/Timolol Rompharm getting into the rest of the body.

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

If you use more Bimatoprost/Timolol Rompharm than you should
If you use more Bimatoprost/Timolol Rompharm 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 Rompharm
If you forget to use Bimatoprost/Timolol Rompharm, 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 Rompharm
Bimatoprost/Timolol Rompharm 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 Bimatoprost/Timolol Rompharm without speaking to your doctor.
The following side effects may be seen with Bimatoprost/Timolol Rompharm:

Very common side effects (may affect more than 1 in 10 people)
<u>Affecting the eye</u>

- 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,
- 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),
- 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 Rompharm. 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 2.85 mg phosphates in each 3 ml of solution which is equivalent to 0.95 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. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Bimatoprost/Timolol Rompharm

Keep Bimatoprost/Timolol Rompharm out of the sight and reach of children.

Do not use Bimatoprost/Timolol Rompharm 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 Rompharm 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 benzalkonium chloride (a preservative), sodium chloride, disodium phosphate heptahydrate, 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.

What Bimatoprost/Timolol Rompharm looks like and contents of the pack
Bimatoprost/Timolol Rompharm is a 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 3 milliliters of solution.
This is enough for 4 weeks' usage.
Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant
S.C. Rompharm Company S.R.L.
1A Eroilor Street, Otopeni 075100, Ilfov County
Roemenië

This medicinal product is authorised in the Member States of the EEA under the following names:

Bulgarije:	Бимасопт 0.3 mg/ml + 5 mg/ml капки за очи, разтвор
Nederland:	Bimatoprost/Timolol Rompharm 0,3 mg/ml + 5 mg/ml oogdruppels, oplossing
Roemenië:	Bimatoprost/Timolol Rompharm 0,3 mg/5 mg/ml picături oftalmice, soluţie

Deze bijsluiter is voor het laatst goedgekeurd in december 2024.