

PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Bimatilol Teva

Eye drops

Composition

Each 1 ml contains:
bimatoprost 0.3 mg
timolol 5 mg (as 6.8 mg timolol maleate)

For information regarding inactive ingredients and allergens, see section 2 under "Important information about some ingredients of the medicine" and section 6 "Additional information".

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have additional questions, refer to the doctor or the pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them even if it seems to you that their illness is similar.

1. What is the medicine intended for?

Bimatilol Teva is intended for lowering intra-ocular pressure in patients with open-angle glaucoma or high pressure in the eye, whose response to local treatment with beta blockers or prostaglandin analogs is insufficient.

Therapeutic class:

Bimatoprost: prostaglandin analogs
Timolol: beta blockers

This medicine contains two different active ingredients that both work to reduce pressure in your eye.

Your eye contains a clear and watery fluid that feeds the eye's interior. The fluid drains out of the eye regularly and new fluid is produced to replace it. If the fluid cannot drain outside sufficiently fast, pressure builds up inside the eye which may eventually impair your eyesight (an illness called glaucoma). Bimatilol Teva acts by reducing the fluid production and also by increasing the amount of drained fluid. This reduces the pressure inside the eye.

2. Before using the medicine

Do not use this medicine if:

- You are sensitive (allergic) to bimatoprost, timolol, beta blockers or to any of the other ingredients in this medicine (listed in section 6 "Additional information").
- You are currently suffering or have suffered in the past from respiratory problems such as asthma and/or severe chronic obstructive pulmonary disease (a lung disease that can cause wheezing, breathing difficulties and/or prolonged cough), or other types of breathing problems.
- You are suffering from heart problems such as low heart rate, heart block or heart failure.

Special warnings regarding the use of the medicine

Before starting treatment with Bimatilol Teva, inform the doctor if you are currently suffering or have suffered in the past from:

- Coronary heart disease (symptoms may include pain or tightness in the chest, shortness of breath or suffocation), heart failure, low blood pressure.
- Heart rate disorders such as slow heartbeat.
- Breathing problems, asthma or chronic obstructive pulmonary disease.
- A disease characterized by reduced blood flow (such as Raynaud's disease or Raynaud's syndrome).
- Overactivity of the thyroid, since timolol can mask signs and symptoms of a thyroid disease.
- Diabetes, since timolol can mask signs and symptoms of low blood sugar level.
- Severe allergic reactions.
- Liver or kidney problems.
- Problems in the eye surface.
- Separation of one of the layers inside the eyeball following surgery for lowering intra-ocular pressure.
- Known risk factors for macular edema (swelling of the retina in the eye which leads to vision deterioration), e.g., a cataract surgery.

Before anesthesia for surgery, inform your doctor that you are using Bimatilol Teva, since timolol may alter the effects of certain medicines that are being used during anesthesia. Bimatilol Teva may cause eyelash growth and darkening, as well as darkening of the skin around the eyelids. The color of the iris may also darken over time.

These changes may be permanent. The change may be more pronounced when you are treating only one eye. When it comes in contact with the skin, Bimatilol Teva may cause hair growth.

Children and adolescents

Bimatilol Teva should not be used in children and adolescents under 18 years old.

Other medicines and Bimatilol Teva

If you are taking or have recently taken other medicines, including non-prescription medicines and food supplements, tell the doctor or the pharmacist. Bimatilol Teva can affect or be affected by other medicines you are using, including other eye drops for the treatment of glaucoma.

Especially inform the doctor or pharmacist if you are taking or intend to take medicines for lowering blood pressure, heart medicines, diabetes medicines, quinidine (used for treatment of heart problems and certain types of malaria) or antidepressants such as fluoxetine and paroxetine.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you might be pregnant or planning to become pregnant, consult your doctor or a pharmacist before using this medicine.

Do not use Bimatilol Teva if you are pregnant, unless your doctor recommends this nonetheless.

Do not use Bimatilol Teva if you are breastfeeding. Timolol may pass into breastmilk. Consult your doctor before taking any medicine during breastfeeding.

Driving and operating machinery

Bimatilol Teva may cause blurry vision in certain patients. Do not drive or operate machinery until these symptoms resolve.

Important information about some ingredients of the medicine

- This medicine contains a preservative called benzalkonium chloride. This medicine contains 0.15 mg benzalkonium chloride in every 3 ml of solution, equivalent to 0.05 mg/ml. Benzalkonium chloride may be absorbed by soft contact lenses and may discolor them. Remove your contact lenses before using this medicine. You may only put them back in your eyes 15 minutes after you have used the medicine.
- Benzalkonium chloride can also cause eye irritation, especially if you have a condition called dry eye or disorders in the cornea (the clear layer in the front of the eye). If you get an abnormal sensation, tingling, or pain in your eye after using this medicine, consult your doctor.
- This medicine contains 2.85 mg phosphate in every 3 ml of solution, equivalent to 0.95 mg/ml (see also section 4 under "Other side effects reported in eye drops containing phosphates").

3. How should you use the medicine?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation. The dosage and treatment regimen will be determined only by the doctor.

The recommended dosage is usually one drop once a day, in the morning or in the evening, in each eye that requires treatment.

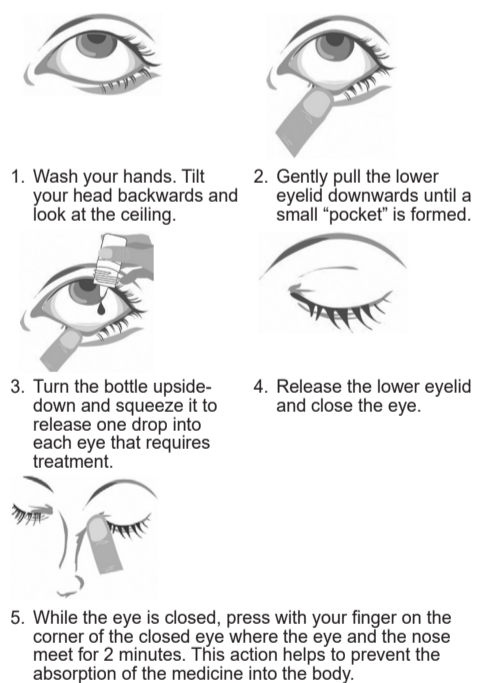
The medicine should be used at the same time each day.

Do not exceed the recommended dose.

Instructions for use:

Do not swallow.

Do not use the bottle if the safety seal on the bottle's neck is broken before first use.



If the drop missed the eye, try again.

After using the medicine, wash your hands thoroughly to clean them of any remaining medicine.

In order to avoid contamination, do not allow the tip of the bottle to come in contact with your eye or with anything else. Replace the cap and close the bottle immediately after use. If you are using Bimatilol Teva together with another eye medicine, wait at least 5 minutes between use of Bimatilol Teva and the other medicine. Use any eye ointment or eye gel last.

If you accidentally take a higher dosage

If you have taken more Bimatilol Teva than necessary, it is unlikely to cause you any serious damage. Apply the next dose at the scheduled time. If you are concerned, speak with the doctor or a pharmacist.

If a child swallowed this medicine by mistake, immediately go to the doctor or the emergency room of the hospital and bring the package of the medicine with you.

If you have forgotten to take the medicine

If you have forgotten to take Bimatilol Teva, apply a single drop as soon as you remember, and then return to your normal treatment routine. Do not apply a double dose in order to compensate for a forgotten dose.

Adhere to the treatment as recommended by the doctor.

If you stop taking the medicine

Bimatilol Teva should be used every day for it to work properly.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

Do not take medicines in the dark! Check the label and the dose every time you take the medicine. Wear glasses if you need them. If you have any other questions regarding use of the medicine, consult the doctor or the pharmacist.

4. Side effects

As with any medicine, using Bimatilol Teva may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Treatment with drops can usually be continued, unless the effects are severe. If you are worried consult a doctor or a pharmacist. Do not stop using Bimatilol Teva without consulting with your doctor.

The following side effects may appear during treatment with Bimatilol Teva:

Very common side effects (may affect more than 1 out of 10 users):

Affecting the eye

Redness

Common side effects

(may affect 1-9 out of 100 users):

Affecting the eye
Burning, itching, tingling, irritation of the conjunctiva (the clear layer of the eye), sensitivity to light, pain in the eye, sticky eyes, dryness in the eyes, foreign body sensation in the eye, small cracks in the eye's external surface with or without an inflammation, difficulty seeing clearly, red and itchy eyelids, hair growth around the eye, eyelid darkening, darkening of the color of the skin around the eyes, eyelashes elongation, eye irritation, watery eyes, swollen eyelids, vision impairment.

Affecting other parts of the body

Rhinitis, headache.

Uncommon side effects (may affect 1-9 out of 1,000 users):

Affecting the eye

Abnormal sensation in the eye, inflammation of the iris, swollen conjunctiva (the clear layer of the eye), painful eyelids, tired eyes, reverse eyelash growth, darkening of the color of the iris, seemingly sunken eyes, eyelid drooping, eyelid shrinking (eyelid moving away from the surface of the eye leading to incomplete closure of the eyelids), eyelid tightness (eyelid skin is tighter), darkening of eyelashes.

Affecting other parts of the body

Shortness of breath.

Side effects with unknown frequency:

Affecting the eye

Cystoid macular edema (swelling of the retina inside the eye, which leads to vision deterioration), swelling of the eye, blurry vision, eye discomfort.

Affecting other parts of the body

Breathing difficulties/wheezing, symptoms of an allergic reaction (swelling, eye redness and skin rash), changes in sense of taste, dizziness, slowing of heart rate, high blood pressure, sleeping difficulties, nightmares, asthma, hair loss, skin discoloration (around the eye), tiredness.

Additional side effects have been observed in patients that used eye drops that contain timolol or bimatoprost; therefore, these may appear upon use of Bimatilol Teva. Like other medicines that are administered into the eyes, timolol is absorbed into the blood. This can cause side effects similar to those that appear due to intravenous and/or oral beta blockers. The chance for side effects due to use of eye drops is lower than medicines taken, for example, by mouth or by injection.

The side effects in the list include effects that have been observed with timolol and bimatoprost when used for treatment of eye problems:

- Severe allergic reactions with swelling and breathing difficulties which may be life-threatening.
- Low blood sugar level.
- Depression, memory loss, hallucinations.
- Fainting, stroke, reduced blood flow to the brain, aggravation of myasthenia gravis (increased muscle weakness), tingling sensation.
- Reduced sensation in the eye surface, double vision, drooping eyelids, separation of one of the layers inside the eyeball following surgery for lowering intra-ocular pressure, inflammation of the eye surface, bleeding in the back of the eye (retinal bleeding), inflammation within the eye, increased blinking.
- Heart failure, heartbeat irregularities or breaks, slow or fast heartbeat, excess of fluids, mostly water building up in the body, chest pain.
- Low blood pressure, swelling or a sensation of cold hands, feet and extremities, caused by blood vessel constriction.
- Cough, worsening of asthma, worsening of the lung disease called chronic obstructive pulmonary disease (COPD).
- Diarrhea, abdominal pain, nausea and vomiting, dyspepsia, dry mouth.
- Red and flaky patches on the skin, skin rash.
- Muscle pain.
- Decreased libido, sexual dysfunction.
- Weakness.
- An increase in blood test results for liver function.

Other side effects reported in eye drops containing phosphates:

If you have severe damage to the clear layer in the front part of the eye (cornea), phosphates may, in very rare cases, cause cloudy patches on the cornea due to calcium accumulation during treatment.

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects

Side effects may be reported to the Ministry of Health by clicking on the link "report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the bottle's label and on the package. The expiry date refers to the last day of that month.
- **Storage conditions: store below 25°C.**

Once opened, solutions can become contaminated which can cause eye infections. Therefore, **the preparation can be used for up to 28 days after first opening the bottle, and no later than the expiry date.** In order to help you remember, mark the date when you opened the bottle in the designated space on the package.

6. Additional information

In addition to the active ingredients, the medicine also contains:

Sodium chloride, dibasic sodium phosphate heptahydrate, citric acid monohydrate, benzalkonium chloride, sodium hydroxide or hydrochloric acid (for pH adjustment), purified water.

What does the medicine look like and what are the contents of the package

Bimatilol Teva is a clear and colorless eye drops solution, in a plastic bottle with a screw-on cap. Each bottle contains 3 ml of solution. This amount is sufficient for 4 weeks.

Name and address of the license holder and manufacturer:

Teva Ltd.,
124 Dvora HaNevi'a Street, Tel Aviv 6944020

The leaflet was revised in June 2022 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 161-23-35256