PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986
The medicine is dispensed with a doctor's prescription only

Bimatoprost Teva

Eye drops, solution

Active ingredient:
Each 1 ml contains:
Bimatoprost 0.3 mg
For information regarding inactive ingredients and allergens in the medicine, see section 2 - "Important information about some of the 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 for treatment of 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?

Bimatoprost Teva is intended for lowering intra-ocular pressure in patients with chronic open-angle glaucoma as a monotherapy or in combination with eye drops containing beta-blocking agents.
Therapeutic class: prostaglandin analogs called prostamides.
The eye contains a clear and watery fluid that nourishes 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 out sufficiently fast, pressure builds up inside the eye. The medicine acts by increasing the amount of fluid drained. This way the pressure inside the eye is reduced. If the high pressure is not reduced, it can lead to an illness called glaucoma and eventually impair your eyesight.

2. Before using the medicine

☒ Do not use this medicine if:
- You are sensitive (allergic) to bimatoprost or to any of the other ingredients this medicine contains (see section 2 – "Important information about some of the ingredients of the medicine" and section 6 - "Additional information").
- You were previously required to stop using eye drops due to side effects that result from the preservative benzalkonium chloride.

❗ Special warnings regarding the use of the medicine

Before starting treatment with Bimatoprost Teva, inform the doctor if:
- You have breathing problems.
- You have liver or kidney problems.
- You previously had a cataract surgery.
- You have dry eyes.
- You have or previously had problems with the cornea (the clear frontal part of the eye).
- You wear contact lenses (see "Important information about some of the ingredients of the medicine").
- You have or previously had low blood pressure or low heart rate.
- You had a viral infection or an inflammation of the eye.

Bimatoprost may cause eyelash growth and darkening, as well as darkening of the skin around the eyelid. The color of the iris may also darken over time. These changes may be permanent. The change may be more evident if you are treating only one eye.

❗ Children and adolescents
Bimatoprost has not been studied in children and adolescents under the age of 18, and is therefore not intended to be used in this population.

❗ Drug-drug interactions
If you are taking or have recently taken other medicines, including non-prescription medicines and food supplements, tell the doctor or the pharmacist.

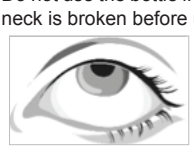
❗ Pregnancy and breastfeeding
If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, ask your doctor or pharmacist for advice before taking any medicine.
Bimatoprost may pass into breastmilk; therefore, you should not breastfeed during treatment with Bimatoprost Teva.

❗ Driving and operating machinery
Your vision may be blurry for a short while immediately after using Bimatoprost Teva. **Do not drive or operate dangerous machinery while using** Bimatoprost Teva until your vision has cleared.

Important information about some of the ingredients of the medicine
Bimatoprost Teva contains a preservative called benzalkonium chloride in amounts of 0.05 mg in each 1 mL. Benzalkonium chloride may be absorbed by soft contact lenses and may cause contact lenses discoloration. Contact lenses should be removed before using this medicine and may be replaced 15 minutes after use.
Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or problems in the cornea (the clear layer in the front of the eye). If you have an abnormal sensation in your eye, itching or pain in the eye after using this medicine, contact the doctor.
Bimatoprost Teva contains phosphate in amounts of 0.95 mg in each 1 mL. If you have a severe injury in the clear layer in the frontal part of the eye (the cornea), phosphates may very rarely cause cloudy patches on the cornea due to calcium accumulation during treatment.

3. How should you use the medicine?

Always use the medicine according to the doctor's instructions.
Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the medicine.
The dosage and treatment regimen will be determined only by the doctor.
Bimatoprost Teva should be used for the eyes only.
The generally accepted dosage is: one drop of Bimatoprost Teva in the evening, once a day, in each eye that requires treatment.
If you are using Bimatoprost Teva alongside another eye medicine, wait at least 5 minutes between using Bimatoprost Teva and the other medicine.
Do not use more than once a day as the treatment's efficiency may be reduced.
Do not exceed the recommended dose.
Instructions for use:
Do not use the bottle if the protective seal on the bottle's neck is broken before use.



1. Wash your hands. Tilt your head backwards and look at the ceiling.

2. Gently pull the lower eyelid downwards until a small "pocket" is formed.

3. Turn the bottle upside-down and squeeze it to release one drop into each eye that requires treatment.

4. Release the lower eyelid and close the eye for 30 seconds.

Wipe excessive fluid running down the cheek.
If a drop has missed the eye, try again.
In order to avoid spreading an infection and prevent eye injury, the tip of the bottle should not be allowed to touch the eye or anything else. The cap should be replaced and the bottle closed immediately after use.

If you accidentally take a higher dosage
If you have used more Bimatoprost Teva than necessary, it is unlikely you will incur any serious damage. Administer the next dose at the scheduled time. If you are concerned, consult 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 use Bimatoprost Teva, administer one drop as soon as you remember, and then return to your normal treatment routine. Do not administer a double dose in order to compensate for a forgotten dose.
Follow the treatment as recommended by the doctor.

If you stop taking the medicine
Bimatoprost Teva should be used every day for it to work properly. If you stop using Bimatoprost Teva, the pressure inside your eye may rise. Therefore, consult a doctor before stopping this treatment.
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 <u>every time</u> 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 Bimatoprost 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.

Very common side effects - side effects that occur in more than one out of ten users:
<u>Eye effects</u>
Eyelashes elongation (up to 45% of the people), slight redness (up to 44% of the people), itching (up to 14% of the people).

Common side effects - side effects that occur in 1-10 out of 100 users:
<u>Eye effects</u>
An allergic reaction inside the eye, eye fatigue, sensitivity to light, darkening of the color of the skin around the eye, eyelash darkening, pain, foreign body sensation in the eye, sticky eyes, darkening of the color of the iris, sharp vision difficulty, irritation, burning, inflamed, red and itchy eyelids, tears, dryness, vision deterioration, blurred vision, swelling in the clear layer that covers the eye surface, small cracks in the eye surface, with or without inflammation.
<u>Body effects</u>
Headaches, a rise in blood tests results that show liver function, rise in blood pressure.

Uncommon side effects - side effects that occur in 1-10 out of 1,000 users:
<u>Eye effects</u>
Cystoid macular edema (swelling of the retina leading to vision deterioration), eye inflammation, retinal bleeding, swollen eyelids, eyelid spasm, redness in the skin around the eye, eyelid contraction (moves away from the eye surface).
<u>Body effects</u>
Nausea, dizziness, weakness, hair growth around the eye.

Side effects with unknown frequency (effects whose frequency has not yet been determined):
<u>Eye effects</u>
Seemingly sunken eyes, discomfort in the eye.
<u>Body effects</u>
Asthma, worsening of asthma, worsening of a lung disease called chronic obstructive pulmonary disease (COPD), shortness of breath, symptoms of an allergic reaction (swelling, eye redness and skin rash), skin discoloration (around the eye).

Other side effects reported in eye drops containing phosphates:
In very rare cases, a number of patients with severe damage to the frontal clear part of the eye (the cornea) have developed cloudy patches on the cornea as a result of calcium accumulation during the 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.
<u>Reporting side effects</u>
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 package. The expiry date refers to the last day of that month.
Storage: Store below 25°C.
After opening the bottle for the first time, it should be stored under 25°C and may be used for up to 28 days but no later than the expiration date.
You should discard the bottle no later than 28 days after opening it for the first time, even if some drops remain. Discarding the bottle will help in preventing infections. In order to help you remember, mark the date when you opened the bottle for the first time in the empty space on the package.
Do not discard any medicine in the sewage or household waste. Ask the pharmacist how to dispose of medicines no longer in use. These measures will help to protect the environment.

6. Additional information

In addition to the active ingredient, the medicine also contains:
Sodium chloride, dibasic sodium phosphate heptahydrate, citric acid monohydrate, benzalkonium chloride (preservative), sodium hydroxide or hydrochloric acid (to adjust pH), purified water

What does the medicine look like and what are the contents of the package
A clear and colorless eye drops solution. The package contains a plastic bottle with a screw-on cap. The bottle is approximately half-full and contains 3 mL of solution. The amount is sufficient for use of up to 4 weeks.

License holder and the address:
Abic Marketing Ltd. P.O. box 8077 Netanya.

Name and address of the manufacturer:
Teva Pharmaceutical Industries Ltd., P.O. box 3190, Petah Tikva.

The format of this leaflet was determined by the Ministry of Health and its content was checked and approved by the Ministry of Health on 11/2018, and has been updated in accordance with the Ministry of Health instructions on 08/2019.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 161-04-35257