



PACKAGE LEAFLET

BEMATORIN 0.01% Eye Drops, Solution
Instilled into the eye(s)
Sterile

Active substance: Each ml contains 0.1 mg bimatoprost.

Excipients: Benzalkonium chloride, disodium EDTA, disodium hydrogen phosphate heptahydrate, citric acid monohydrate, sodium chloride, hydrochloric acid or sodium hydroxide, water for injection.

Read all of this PACKAGE 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, ask your doctor or pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others.*
- *During the period when you take this medicine, tell your doctor that you take this drug when you go to doctor or hospital.*
- *Exactly comply with what is written in this leaflet. Do not take either a **higher** or **lower** dose other than recommended to you for this medicine.*

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1. WHAT BEMATORIN IS AND WHAT IT IS USED FOR

BEMATORIN is an eye drop solution available in a plastic bottle containing 2.5 ml solution.

BEMATORIN contains bimatoprost as active substance which belongs to a group of medicines called prostamides.

BEMATORIN is used to reduce high pressure in the eye. This medicine may be used on its own or with other drops called beta-blockers which also reduce pressure.

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. BEMATORIN works by increasing the amount of liquid that is drained. This reduces the pressure inside the eye. If the high pressure is not reduced, it could lead to a disease called glaucoma and eventually damage your sight.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE BEMATORIN **DO NO USE BEMATORIN**

- If you are allergic to bimatoprost or any of the other ingredients of this medicine.
- If you have had to stop using eye drops in the past because of a side effect of the preservative benzalkonium chloride.



TAKE SPECIAL CARE WITH BEMATORIN

- If you have been told that you are at risk of macular edema
- If you have any breathing problems
- If you have liver or kidney problems
- If you have had a cataract surgery in the past
- If you have dry eye
- If you have or have had any problems with your cornea (front transparent part of the eye)
- If you wear contact lenses (see “Important information regarding some excipients in BEMATORIN”)
- If you have or have had low blood pressure or low heart rate
- If you have had a viral infection or inflammation of the eye
- If you are using another medicine to reduce high intraocular pressure
- If you are using another medicine containing benzalkonium chloride

BEMATORIN may cause your eyelashes to darken and grow, and cause the skin around the eyelid to darken too. The color of your iris may also go darker over time. These changes may be permanent. The changes may be more noticeable if you are only treating one eye.

There is a potential for hair growth to occur in areas where BEMATORIN solution comes repeatedly in contact with the skin surface. Thus, it is important to apply BEMATORIN as instructed and avoid it running onto the cheek or other skin areas.

Bimatoprost 0.1 mg/ml eye drops have not been tested in children under the age of 18 and therefore should not be used by patients under 18 years.

The preservative in BEMATORIN, benzalkonium chloride may cause eye irritation and is also known to discolor soft contact lenses. If you wear contact lenses, remove contact lenses prior application of BEMATORIN and wait at least 15 minutes before reinsertion.

If these warnings apply to you, even at any time in the past, please consult your doctor.

Using BEMATORIN with food and drinks

BEMATORIN is not expected to interact with food and drinks.

Pregnancy

Consult your doctor or pharmacist before using this medicine.

BEMATORIN should not be used during pregnancy unless recommended by your doctor.

During your treatment, if you realize that you are pregnant, consult to your doctor or pharmacist immediately.

Breastfeeding

Consult your doctor or pharmacist before using this medicine.

BEMATORIN can pass into breast milk, therefore it should not be used during breastfeeding.

Driving and using machines

BEMATORIN may cause short-term blurred vision. Do not drive or use machinery until your vision improves.

Important information regarding some excipients in BEMATORIN

BEMATORIN contains benzalkonium chloride, which may cause eye irritation. Avoid contact of the medicine with soft contact lenses. Before instillation, remove your contact lenses and wait at least 15 minutes before putting them back on. This excipient is known to discolor soft contact lenses.

Using other medicines

If you use BEMATORIN together with another eye drop medication, the medications should be administered at least 5 minutes apart.

Please inform your doctor or pharmacist if you are using or have recently used any other medicines, including medicines obtained without prescription.

3. HOW TO USE BEMATORIN

Instructions for proper use and dose/frequency of administration

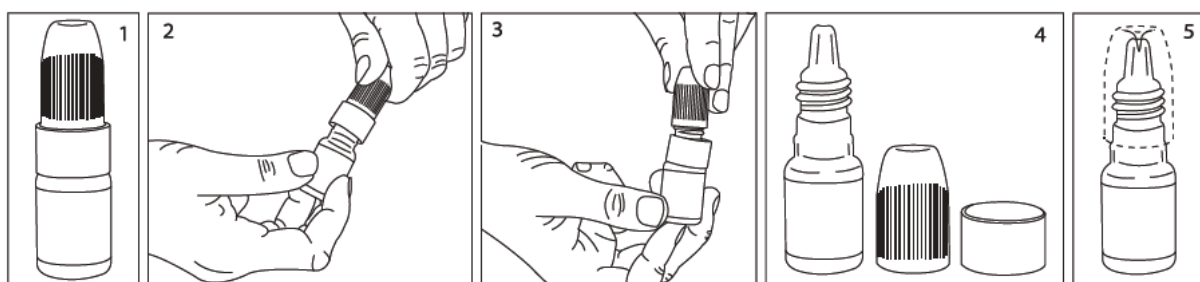
Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Used alone or in addition to other medications, instill one drop of BEMATORIN 0.01% Eye Drops, Solution to the affected eye once daily, in the evening.

Method and route of administration

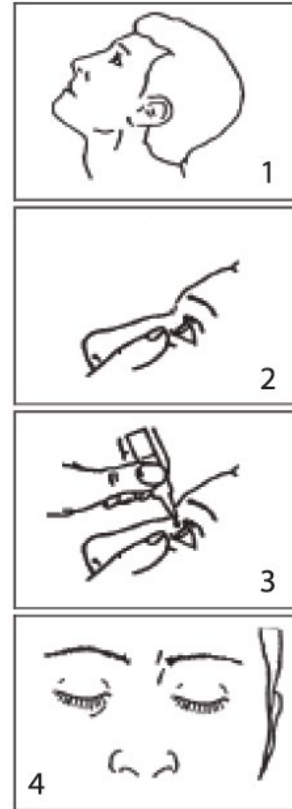
BEMATORIN is applied to the eye via instillation.

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



- Open the cap of the bottle.
- Remove the ring under the cap (see Figure 3 and Figure 4).
- Close the cap again without the ring. The plastic pin inside the cap will pierce the tip of the bottle (see Figure 5).

1. Wash your hands. Look at the ceiling by tilting your head back.
2. Gently pull your lower eyelid downwards to create a small pocket.
3. Turn the bottle upside down and squeeze one drop into the eye that needs treatment.
4. Release your lower eyelid and keep your eye closed for 30 seconds.



Wipe off any excess that runs down the cheek. 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.

Follow these instructions unless your doctor advises you differently.

If you use BEMATORIN with another eye medicine, wait at least 5 minutes between two applications.

Different age groups

Use in children

The efficacy and safety of bimatoprost 0.1 mg/ml eye drops in children have not been determined. BEMATORIN should not be used in people under 18 years of age.

Use in the elderly

No dose adjustment is required in elderly patients.

Special conditions for use

Liver/Kidney failure

Since bimatoprost 0.1 mg/ml eye drops have not been investigated in patients with liver or kidney failure, tell your doctor if you are in these patients group and please use BEMATORIN with caution.

If you have an impression that the effect of BEMATORIN is too strong or too weak, please contact your doctor or pharmacist.



If you used more BEMATORIN than you should

If you use more BEMATORIN than you should, it is not likely to cause any harm. Apply your next dose at your regular time.

If you have used more BEMATORIN than you should, talk to a doctor or pharmacist.

If you forget to use BEMATORIN

If you forget to use BEMATORIN, apply one drop as soon as you remember. Apply your next dose at your regular time.

Do not take a double dose to make up for a forgotten dose.

If you stop using BEMATORIN

In order for BEMATORIN to be effective, it must be used regularly every day. When you stop using BEMATORIN, the pressure inside your eye may increase, so consult your doctor before ending your treatment.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, BEMATORIN may cause side effects in individuals who are sensitive to its ingredients.

The frequencies of side effects are as follows:

Very common	: affects more than 1 in 10 patients
Common	: affects less than 1 in 10 patients but more than 1 in 100 patients
Uncommon	: affects less than 1 in 100 patients but more than 1 in 1,000 patients
Rare	: affects less than 1 in 1,000 patients but more than 1 in 10,000 patients
Very rare	: affects less than 1 in 10,000 patients
Unknown	: cannot be estimated from available data

Very common side effects

- Slight redness

Common side effects

- Small breaks in the surface of the eye, with or without inflammation
- Irritation
- Itchy eyes
- Longer eyelashes
- Eye pain
- Irritation when drop is put in the eye
- Red eyelids
- Itchy eyelids
- Darker skin color around the eye
- Hair growth around the eye



Uncommon side effects

- Headache
- Tired eye
- Blurred vision
- Swelling of the surface of the eye
- Darker iris color
- Loss of eyelashes
- Feeling of sickness
- Dry skin
- Crusting on the edge of the eyelid
- Swelling of the eyelid
- Itching

Very rare side effects

- Cloudy patches on the clear layer at the front of the eye

In addition to the side effects for bimatoprost 0.1 mg/ml eye drops, the following side effects have been seen with 0.3 mg/ml strength of bimatoprost eye drops:

Common side effects

- Burning
- An allergic reaction in the eye (hypersensitivity reaction)
- Inflamed eyelids
- Difficulty in seeing clearly
- Worsening of vision
- Swelling of the see-through layer which covers the surface of the eye
- A feeling that something is in your eye
- Dryness
- Sensitivity to light
- Tears
- Sticky eyes
- Darker eyelashes
- Increased blood pressure
- An increase in blood-test results that show how your liver is working

Uncommon side effects

- Dizziness
- Retinal bleeding
- Inflammation within the eye
- Cystoid macular edema (swelling of the retina within the eye leading to worsening vision)
- Eyelid twitching
- Skin redness around the eye
- Weakness

Side effects where the frequency is not known

- Eyeballs that seem to be located deeper in the eye cavity



If you experience any side effects not mentioned in this leaflet, inform your doctor or pharmacist.

Reporting of side effects

If you get any side effects including any possible side effects not listed in this leaflet, talk to your doctor, pharmacist or nurse. 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 BEMATORIN

Keep BEMATORIN out of the reach and sight of children and in its original package.

Store below 25°C at room temperature.

Once the bottle is first opened, it should be used within 4 weeks.

Use in accordance with the expiry date.

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.

Do not use BEMATORIN after the expiry date which is stated on the package.

Marketing Authorization Holder

DEVA Holding A.Ş.
Küçükçekmece – İSTANBUL / TÜRKİYE

Manufacturer

DEVA Holding A.Ş.
Kartepe – KOCAELİ / TÜRKİYE

This package leaflet was approved on 21/12/2017.