The format of this leaflet has been decided by the Ministry of Health, and its content has been checked and approved by the Ministry in November 2018

Patient leaflet in accordance with the Pharmacists' Regulations (Medicinal Products) - 1986

Prescription only medicine

Bimatoprost, eye drops, solution

Active ingredient: Bimatoprost 0.03%
Inactive ingredients and allergens in the product: see section 6, "Further Information"

Read the entire leaflet carefully before using the medicine. This leaflet contains brief information on the medicine. If you have further questions, refer to the doctor or pharmacist.
This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it appears to you that they have a similar illness.

1. What is the medicine intended for?
Bimatoprost S.K. is used to reduce intraocular pressure in patients with chronic open-angle glaucoma, as a single treatment or in combination with beta-blockers containing drops.

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 fluid is produced to replace it. If the liquid cannot drain out quickly enough, the pressure inside the eye increases.
The medicine works by increasing the amount of liquid that is drained. In this way, the pressure inside the eye is reduced. If the high pressure is not reduced, it could lead to a disease called glaucoma, and can eventually damage your sight.

Therapeutic group: Prostaglandin analogue.

2. Before using the medicine

Do not use this medicine if:

- You are sensitive (allergic) to Bimatoprost or to any of the other ingredients contained in the medicine..
- You have had to stop using eye drops in the past because of side effects due to the preservative benzalkonium chloride.

Before starting treatment with Bimatoprost S.K., tell the doctor if:

- You have breathing problems
- You have liver or kidney problems
- You have had a cataract surgery in the past
- You have dry eye
- You have, or have had in the past, retinal problems (the transparent front part of the eye)

- You wear contact lenses (see "Important information on some of the ingredients of Bimatoprost S.K. 0.3 mg/ml")
- You have, or have had, low blood pressure or low heart rate
- You have had a viral infection or inflammation of the eye

Bimatoprost S.K. may cause darkening and growth of the eyelashes, as well as darkening of the skin around the eyelid. The color of the iris may darken over time. These changes may be permanent. It is possible that the change will be more noticeable if you are treating only one eye.

Children and adolescents
Bimatoprost S.K. has not been tested in children and adolescents under the age of 18, and therefore is not intended for use by this population.

If you are taking, or have recently been taking other medicines, including non-prescription medicines and dietary supplements, tell the doctor or pharmacist.

Pregnancy and breastfeeding:
If you are pregnant or breastfeeding, think that you might be pregnant, or are planning to become pregnant, consult your doctor or pharmacist before taking any medicines.
Bimatoprost S.K. may pass into breast milk, and therefore you should not breastfeed during treatment with Bimatoprost S.K..

Driving and the use of machinery
Your vision may be blurred for a short time immediately after using Bimatoprost S.K. **Do not drive or operate dangerous machinery while using** Bimatoprost S.K., until you can see clearly again.

Important information on some of the ingredients of Bimatoprost S.K. 0.3 mg/ml
Do not use the drops while wearing contact lenses. Wait 15 minutes after using the eye drops before wearing the contact lenses again. A preservative in Bimatoprost S.K., called benzalkonium chloride, may cause eye irritation, and may change the color of soft contact lenses.

3. How is the preparation used?

Always use as instructed by the doctor. If you are not certain, check with your doctor or pharmacist.

The dose and treatment will be determined only by the doctor.

Bimatoprost S.K. should be only applied to the eye. The usual dose is: one drop of Bimatoprost S.K. in the evening, once a day, in each eye requiring treatment.

If you are using Bimatoprost S.K. in conjunction with another ophthalmic medicine, wait at least five minutes between using Bimatoprost S.K. and the use of the other ophthalmic medicine.

Do not use more than once a day, because the effectiveness of the treatment may be reduced.

Instructions for use:
Do not use the bottle if the protective seal on the bottle is broken before use.

1. 
2. 
3. 
4. 

1. Wash your hands. Tilt your head back, and look at the ceiling.
2. Gently pull your lower eyelid down to create a kind of little “pocket”.
3. Turn the bottle upside down and squeeze it in order to apply a single drop in each eye requiring treatment.
4. Release the lower eyelid and close the eye for 30 seconds.

Immediately after applying the drop into the eye, use your middle finger to press against the inner corner of the eye. Maintain pressure for 1 to 2 minutes after the application of the drop into the eye. This action helps to prevent the medicine being absorbed into the body, thus helping to prevent side effects.

Wipe off any excess that runs down the cheek.
If the drop misses your eye, try again.

After using the medicine, wash your hands well in order to remove any residue of the medicine.

To prevent the spread of infection, and prevent damage to the eye, do not let the tip of the bottle touch your eye or anything else. Replace the cap and close the bottle immediately after use. Do not use the same bottle of medicine for more than one person.

The bottle of eye drops may not be full. This is to allow better control over the rate of dripping.

If you have taken too high a dose accidently
If you have used more Bimatoprost S.K. than required, it is unlikely that any serious harm will be caused. Apply the next dose at the usual time. If you are worried, consult the doctor or pharmacist.
If a child has accidently swallowed the medicine , refer immediately to a doctor or hospital emergency room, taking the medicine package with you.

If you have forgotten to take the medicine
If you have forgotten to use Bimatoprost S.K., apply one drop as soon as you remember, and then return to the usual treatment routine. Do not use a double dose in order to compensate for a dose that has been forgotten.
Make sure you adhere to the treatment, as instructed by the doctor.

If you stop using the medicine
Bimatoprost S.K. should be used every day for it to work properly. If you stop using Bimatoprost S.K., the pressure in your eye may increase, therefore consult your doctor before stopping this treatment.

Do not take medicines in the dark! Check the label and the dose <u>each time</u> you take a medicine. Wear glasses if you need them.

If you have further questions with regard to use of the medicine, consult a doctor or pharmacist.

4. Side effects

As with any medicine, the use of Bimatoprost S.K. may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.
If you do suffer from side effects, speak to the doctor or pharmacist. This includes side effects that are not listed in this leaflet.

Very common side effects
Side effects that may affect more than one user out of 10 users

<u>Affecting the eye</u>

- Longer eyelashes (up to 45% of users)
- Slight redness (up to 44% of users)
- Itchy eyes (up to 14% of users)

Common side effects
Affecting 1 to 9 users out of 100 users

<u>Affecting the eye</u>

- Allergic reaction in the eye
- Tired eyes
- Sensitivity to light
- Darker skin color around the eye
- Darker eyelashes
- Pain
- A feeling that something is in your eye
- Sticky eyes
- Darker iris color
- Difficulty in seeing clearly
- Irritation
- Burning
- Inflamed, red and itchy eyelids
- Tears
- Dryness
- Worsening of vision
- Blurred vision
- Swelling of the see-through layer which covers the surface of the eye
- Small breaks in the surface of the eye, with or without inflammation

<u>Affecting the body</u>

- Headaches
- An Increase in blood test results that show the liver function
- Increased blood pressure

Uncommon side effects
Affecting 1 to 9 users out of 1000 users

Affecting the eye

- Cystoid macular edema (swelling of the retina within the eyesleading to a worsening of vision)
- Inflammation of the eye
- Retinal bleeding
- Swollen eyelids
- Eyelid twitching
- Eyelid shrinking, moving away from surface of the eye
- Skin redness around the eye

Affecting the body

- Nausea
- Dizziness
- Weakness
- Hair growth around the eye

Side effects whose frequency is unknown (side effects whose frequency has not yet been determined)

Affecting the eye

- Eyes appear sunken

Affecting the body

- Asthma
- Worsening of asthma
- Worsening of the lung disease called chronic obstructive pulmonary disease (COPD)
- Shortness of breath
- Symptoms of allergic reaction (swelling, redness of the eye, and rash of the skin)

Other side effects that have been reported for 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.

If any of the side effects gets serious, or if you notice any side effects not mentioned in this leaflet, you should consult your doctor.

Side effects can be reported to the Ministry of Health by clicking the link for "Reporting side effects due to medicinal treatment", on the home page of the Ministry of Health website (www.health.gov.il), which directs you to an online form for reporting side effects, or by using the following link: https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il

5. How to store the preparation

Avoid poisoning! This medicine and any other medicine, should be kept in a safe place out of reach of children and/or infants, in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.

Do not use this medicine after the expiry date (exp. Date) which is stated on the bottle.
The expiry date refers to the last date of the month.
Storage Conditions: Below 30ºC
After first opening of the bottle, it should be stored below 25°C and can be used for up to 28 days, but not after the expiry date.
You must throw away the bottle no later than 28 days after first opening it, even if drops still remain. This will help prevent infections. In order to help you remember, write the date that you first opened the bottle on the box.

6. Further information
In addition to the active ingredient, the preparation also contains:
Sodium chloride, Disodium hydrogen phosphate heptahydrate, citric acid monohydrate, benzalkonium chloride (preservative), hydrochloric acid or sodium hydroxide (to adjust pH), Water for injection

Do not throw away any medicines via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

What does the medicine look like, and contents of the pack?
Bimatoprost S.K. is a , colorless, clear and watery eye drops solution, in a package containing a plastic bottle with a cap.
The bottle contains 3 milliliters of solution. This quantity is sufficient for use of up to 4 weeks.

License Holder: K.S. Kim International Ltd., 7 Jabotinsky St., Ramat Gan
Manufacturer: RAFARM S.A., 12 Korinthou str. 15451 N. Psychiko, Greece

This leaflet was checked and approved by the Ministry of Health in November 2018.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 161-03-35010-00

For the sake of simplification and ease of reading, this leaflet has been written in masculine form. Nonetheless, the medicine is intended for both men and women.