

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### **Bimatoprost Sandoz® 0,3 mg/ml, oogdruppels, oplossing** Bimatoprost

**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 further questions, 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 {[Nationally completed name]} is and what it is used for
2. What you need to know before you use {[Nationally completed name]}
3. How to use {[Nationally completed name]}
4. Possible side effects
5. How to store {[Nationally completed name]}
6. Contents of the pack and other information

#### **1. What [Nationally completed name] is and what it is used for**

[Nationally completed name] is an antiglaucoma preparation. It belongs to a group of medicines called prostamides.

[Nationally completed name] 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. This medicine 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 [Nationally completed name]**

##### **Do not use [Nationally completed name]:**

- if you are allergic to bimatoprost or any of the other ingredients of this medicine (listed in section 6).
- if you have had to stop using eye drops in the past because of a side effect of the preservative benzalkonium chloride.

#### **Warnings and precautions**

Talk to your doctor or pharmacist before using [Nationally completed name].

Talk to your doctor, if:

- You have any 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 any problems with your cornea (front transparent part of the eye).
- You wear contact lenses (see “Important information about some of the ingredients of [Nationally completed name]”).
- You have or have had low blood pressure or low heart rate.
- You have had a viral infection or inflammation of the eye.

During treatment, [Nationally completed name] 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 [Nationally completed name]. [Nationally completed name] 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.

### **Children and adolescents**

[Nationally completed name] has not been tested in children under the age of 18 and therefore [Nationally completed name] should not be used by patients under 18 years.

### **Other medicines and [Nationally completed name]**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

### **Pregnancy, breast-feeding and fertility**

If you are pregnant or breast-feeding, think you might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking any medicine.

[Nationally completed name] may get into breast milk so you should not breast-feed while you are using [Nationally completed name].

### **Driving and using machines**

Your sight may become blurred for a short time just after using [Nationally completed name]. You should not drive or use machines until your sight is clear again.

### **[Nationally completed name] contains benzalkonium chloride**

This medicine contains 0.05 mg benzalkonium chloride in each 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.

### **[Nationally completed name] contains phosphates**

This medicine contains 0.95 mg phosphates in each 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 [Nationally completed name]**

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

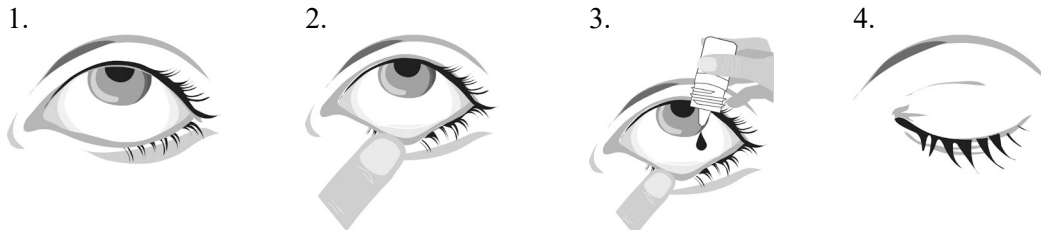
[Nationally completed name] should only be applied to the eye. The recommended dose is one drop of [Nationally completed name] in the evening, once daily in each eye that needs treatment.

If you use [Nationally completed name] with another eye medicine, wait at least five minutes between using [Nationally completed name] and the other eye medicine.

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

#### 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 for 30 seconds.

Wipe off any excess that runs down the cheek.

If a drop misses your eye, try again.

To help prevent infections, 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 more [Nationally completed name] than you should

If you use more [Nationally completed name] 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 [Nationally completed name]

If you forget to use [Nationally completed name], 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 [Nationally completed name]

[Nationally completed name] should be used every day to work properly. If you stop using [Nationally completed name] the pressure inside your eye may go up, therefore talk to your doctor before stopping this treatment.

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

#### 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Very common side effects** (may affect more than 1 in 10 people)

#### Affecting the eye region

- Longer eyelashes (up to 45% of people)
- Slight redness (up to 44% of people)
- Itchiness (up to 14% of people)
- 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

- An allergic reaction in the eye
- Tired eyes
- Sensitivity to light
- Darker skin colour around the eye
- Darker eyelashes
- Pain
- A feeling that something is in your eye
- Sticky eyes
- Darker iris colour
- 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

##### Affecting the body

- Headaches
- An increase in blood-test results that show how your liver is working
- Increased blood pressure

#### **Uncommon side effects** (may affect up to 1 in 100 people)

##### Affecting the eye

- Cystoid macular oedema (swelling of the retina within the eye leading to worsening vision)
- Inflammation within the eye
- Retinal bleeding
- Swollen eyelids
- Eyelid twitching
- Eyelid has moved away from surface of eye
- Skin redness around the eye

##### Affecting the body

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

**Not known** (frequency cannot be estimated from the available data)

Affecting the eye

- Ocular discomfort

Affecting the body

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

**Other side effects reported with 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.

**Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store {[Nationally completed name]}**

Keep this medicine out of the sight and reach of children.

Do not use this medicine 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.

You must throw away the bottle, at the latest, four weeks after you first opened it, even if there are still some drops left. This will prevent infections. To help you remember, write down the date you opened it in the space on the box.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

**6. Contents of the pack and other information**

**What {[Nationally completed name]} contains**

- The active substance is bimatoprost. One ml of solution contains 0.3 mg bimatoprost. One drop contains approximately 7.5 micrograms bimatoprost.
  - The other ingredients are benzalkonium chloride (preservative), citric acid monohydrate, disodium phosphate heptahydrate, sodium chloride and purified water, sodium hydroxide or hydrochloric acid.
- See section 2 [Nationally completed name] contains benzalkonium chloride and [Nationally completed name] contains phosphates.

**What {[Nationally completed name]} looks like and contents of the pack**

{[Nationally completed name]} is a clear, colourless solution, practically free from particles in a pack containing either 1 plastic bottle or 3 plastic bottles each with a screw cap. Each bottle is approximately half full and contains either 2.5 millilitres or 3 millilitres 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**

##### **Houder van de vergunning voor het in de handel brengen**

Sandoz B.V., Veluwezoom 22, 1327 AH Almere, Nederland

##### **Fabrikanten**

S.C. Rompharm Company S.R.L.  
Eroilor Street, no. 1A  
Otopeni 075100, Ilfov., Roemenië

Salutas Pharma GmbH  
Otto-von-Guericke Allee 1  
39179 Barleben  
Duitsland

Lek Pharmaceuticals d.d.  
Verovškova 57  
1526 Ljubljana  
Slovenië

##### **In het register ingeschreven onder:**

RVG 113250.

##### **Dit geneesmiddel is geregistreerd in lidstaten van de EEA onder de volgende namen:**

Oostenrijk	Bimatoprost Sandoz 300 Mikrogramm/ml – Augentropfen
Duitsland	Bimatoprost 1 A Pharma 0,3 mg/ml Augentropfen
Finland	Bimatoprost Sandoz
Frankrijk	BIMATOPROST SANDOZ 0,3 mg/ml, collyre en solution
Nederland	Bimatoprost Sandoz 0,3 mg/ml, oogdruppels, oplossing
Portugal	Bimatoprost Sandoz
Verenigd Koninkrijk	Bimatoprost Sandoz 300 mcg/ml Eye Drops

**Deze bijsluiter is voor het laatst goedgekeurd in december 2021.**