

Approved Patient Information Leaflet for Medicines for Human Use:

BIMAPRES 0,01 %

SCHEDULING STATUS: S4

BIMAPRES 0,01 % eye drops, solution

Bimatoprost

Read all of this leaflet carefully before you start taking BIMAPRES 0,01 %

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your health care provider.
- BIMAPRES 0,01 % has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

1. What BIMAPRES 0,01 % is and what it is used for
2. What you need to know before you take BIMAPRES 0,01 %
3. How to take BIMAPRES 0,01 %
4. Possible side effects
5. How to store BIMAPRES 0,01 %
6. Contents of the pack and other information

1. What BIMAPRES 0,01 % is and what it is used for

BIMAPRES 0,01 % is an antiglaucoma preparation. It belongs to a group of medicines called prostamides.

BIMAPRES 0,01 % eye drops are 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 BIMAPRES 0,01 %

Do not use BIMAPRES 0,01 %

- if you are hypersensitive (allergic) to bimatoprost or any of the other ingredients of BIMAPRES 0,01 % (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

Special care should be taken with BIMAPRES 0,01 %:

- 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 “BIMAPRES 0,01 % contains benzalkonium chloride”)
- 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

BIMAPRES 0,01 % may 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 over time. These changes may be permanent. The change may be more noticeable if you are only treating one eye.

Hair may grow in areas where BIMAPRES 0,01 % solution has been repeatedly in contact with the skin surface. This is why it is important to apply BIMAPRES 0,01 % as instructed and to avoid it running onto the cheek or other skin areas.

Children and adolescents

BIMAPRES 0,01 % has not been tested in children under the age of 18 and therefore should not be used by patients under 18 years.

Other medicines and BIMAPRES 0,01 %

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your health care provider for advice before taking this medicine.

The safety of BIMAPRES 0,01 % in pregnancy has not been established. BIMAPRES 0,01 % should not be used during pregnancy unless your doctor still recommends it.

BIMAPRES 0,01 % may get into breast milk so you should not breastfeed while you are taking BIMAPRES 0,01 %.

Driving and using machines

When you use BIMAPRES 0,01 % your vision may become blurred for a short time or you may feel dizzy. If this happens to you, do not drive or use any tools or machines until your vision becomes clear again or until you feel better.

It is not always possible to predict to what extent BIMAPRES 0,01 % may interfere with your daily activities. You should ensure that you do not engage in activities requiring mental alertness, judgment and/or sound coordination and vision e.g. driving, riding, flying, sailing or operating machines/equipment until you are aware of the measure to which BIMAPRES 0,01 % affects you.

BIMAPRES 0,01 % contains benzalkonium chloride

This medicine contains 0,2 mg benzalkonium chloride (a preservative) in each 1 mL of solution which is equivalent to 0,02 % (*m/v*).

Do not use the drops when you are wearing your lenses. 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.

3. How to use BIMAPRES 0,01 %

Do not share medicines prescribed for you with any other person.

Always use BIMAPRES 0,01 % exactly as your health care provider has told you.

Check with your health care provider if you are not sure.

The usual dose is one drop of BIMAPRES 0,01 % in each eye that needs treatment, once every day, in the evening, following the instructions for use below (see "Instructions for use").

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

Duration of administration

Your doctor will tell you how long your treatment with BIMAPRES 0,01 % will last.

Do not stop treatment early. If you have the impression that the effect of BIMAPRES 0,01 % is too strong or too weak, tell your doctor or pharmacist.

Method of administration

BIMAPRES 0,01 % should only be applied to the eye

If you use BIMAPRES 0,01 % with another eye medicine, wait at least five minutes between using BIMAPRES 0,01 % and the other eye medicine.

Instructions for use

1.



2.



3.



4.



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.

If a drop misses your eye, try again.

Wipe off any excess that runs down the cheek.

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 BIMAPRES 0,01 % than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you use more BIMAPRES 0,01 % 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 put too many drops in your eye or swallow any of the contents of the container, among other effects, you may become nauseous, light-headed or feel very tired.

If you forget to use BIMAPRES 0,01 %

If you forget to use BIMAPRES 0,01 %, use a single drop as soon as you remember, and then go back to your regular routine. Do not take a double dose to make up for forgotten individual doses.

If you stop using BIMAPRES 0,01 %

BIMAPRES 0,01 % should be used every day to work properly. If you stop using BIMAPRES 0,01 % the pressure inside your eye may go up, therefore talk to your health care provider before stopping this treatment.

If you have any further questions on the use of this medicine, ask your health care provider.

4. Possible side effects

BIMAPRES 0,01 % can have side effects.

Not all side effects reported for BIMAPRES 0,01 % are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using BIMAPRES 0,01 %, please consult your health care provider for advice.

Tell your doctor if you notice any of the following:

Frequent side effects

Affecting the eye

- Slight redness
- Small breaks in the surface of the eye, with or without inflammation
- Irritation
- Itchy eyes
- Longer eyelashes
- Irritation, when drop is put in the eye
- Eye pain
- Red and itchy eyelids (Prostaglandin analogue periorbitopathy)
- Cloudy, blurry or dim vision, troubling seeing at night, eyes sensitive to light (cataract)

Affecting the skin

- Red and itchy eyelids
- Darker skin colour around the eye
- Hair growth around the eye
- Abnormal hair growth around the eyes (Hypertrichosis)

Less frequent side effects

Affecting the eye

- Darker iris colour
- Tired eye
- Swelling of the surface of the eye
- Blurred vision
- Loss of eye lashes

Affecting the skin

- Dry skin
- Crusting on the edge of the eyelid
- Swelling of the eyelid
- Itching
- Light to dark colored or brownish-black skin discoloration around the eye lids, abnormal hair growth

Affecting the body

- Headache
- Feeling of sickness
- Peripheral oedema (swelling in the arms and legs)

Side effects where the frequency is not known

Affecting the eye

- Macular oedema (swelling of the retina at the back of the eye which may lead to worsening vision)
- Darker eyelid colour
- Eyes appear sunken
- Dryness
- Sticky eyes
- A feeling that something is in your eye
- Swelling of the eye
- Increasing tears
- Ocular discomfort
- Sensitivity to light

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)
- Dizziness
- Increased blood pressure
- Skin discoloration (periocular)

In addition to the side effects for BIMAPRES 0,01 %, the following side effects have been seen with another medicine containing a higher strength of bimatoprost (0,3 mg/mL):

- Ocular burning
- An allergic reaction in the eye
- Inflamed eyelids
- Difficulty in seeing clearly
- Worsening of vision
- Swelling of the see-through layer that covers the eye
- Tears
- Darker eyelashes
- Retinal bleeding
- Inflammation within the eye
- Cystoid macular oedema (swelling of the retina within the eye leading to worsening vision)
- Eyelid twitching
- Eyelid shrinking, moving away from surface of the eye
- Skin redness around the eye
- Weakness
- An increase in blood-test results that show how your liver is working

Other side effects reported with eye drops containing phosphates

Less frequently, 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 you notice any side effects not mentioned in this leaflet, please inform your health care provider.

Reporting of side effects

If you get side effects, talk to your health care provider. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of BIMAPRES 0,01 %.

Suspected side effects can also be reported directly to the Holder of the Certificate of Registration via medsafety@austell.co.za

5. How to store BIMAPRES 0,01 %

- Store all medicines out of reach of children.
- Store unopened container at or below 25 °C in the original carton, until required for use.
- Opened container must be stored at or below 25 °C. Do not use more than 28 days after opening.
- Once opened, solutions may become contaminated, which can cause eye infections. Therefore, you must throw away the bottle 4 weeks (28 days) after you first opened it, even if some solution is left. To help you remember, write down the date that you opened it in the space on the carton.
- Do not use this medicine after the expiry date which is printed on the carton and bottle after EXP. The expiry date refers to the last day of that month.
- Keep bottle tightly closed when you are not using it to prevent contamination.
- Return all unused medicine to your pharmacist.

- Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

6. Contents of the pack and other information

What BIMAPRES 0,01 % contains

- The active substance is bimatoprost. One mL of solution contains 0,1 mg bimatoprost.
- The other ingredients are:
 - benzalkonium chloride (preservative)
 - citric acid monohydrate
 - dibasic sodium phosphate heptahydrate
 - purified water
 - sodium chloride
 - sodium hydroxide or hydrochloric acid (for pH-adjustment)

What BIMAPRES 0,01 % looks like and contents of the pack

BIMAPRES 0,01 % eye drops, is a colourless solution that is a practically clear and practically free of particles.

BIMAPRES 0,01 % eye drops, 3 mL solution is filled in a 5 mL white LDPE bottle with white LDPE dropper insert, and closed with a bluish green, tamper-proof HDPE screw cap. Subsequently, the bottle is packed into the respective folding carton together with the leaflet.

The following pack sizes are available: cartons containing 1 or 3 bottles of 3 mL solution. Not all pack sizes may be marketed.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

Professional Information for this medicine is available on the following URL:

<https://austell.co.za/product-info/>

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