

BIMTOP™ EYE DROPS

(bimatoprost 0.3 mg per mL)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about BIMTOP eye drops. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using BIMTOP eye drops against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What BIMTOP eye drops are used for

BIMTOP eye drops are used to lower raised pressure in the eye and to treat glaucoma.

Glaucoma is a condition in which the pressure of fluid in the eye may be high. However, some people with glaucoma may have normal eye pressure. Glaucoma is usually caused by a build up of the fluid which flows through the eye. This build up occurs because the fluid drains out of your eye more slowly than it is being pumped in. Since new fluid continues to enter the eye, joining the fluid already there, the pressure continues to rise. This raised pressure may damage the back of the eye resulting in gradual loss of sight. Damage can progress so slowly that the person is not aware of this gradual loss of sight. Sometimes even normal eye

pressure is associated with damage to the back of the eye.

There are usually no symptoms of glaucoma. The only way of knowing that you have glaucoma is to have your eye pressure, optic nerve and visual field checked by an eye specialist or optometrist. If glaucoma is not treated it can lead to serious problems, including total blindness. In fact, untreated glaucoma is one of the most common causes of blindness.

BIMTOP eye drops lower the pressure in the eye by helping the flow of fluid out of the eye chamber.

This medicine can be used alone or together with other eyedrops/ medicines to lower raised pressure within your eyes.

Although BIMTOP eye drops help control your condition, they will not cure it.

This medicine is only available with a doctor's prescription.

Ask your doctor if you have any questions about why BIMTOP eye drops have been prescribed for you.

Your doctor may have prescribed it for another reason.

For more information about glaucoma, contact Glaucoma Australia Inc (telephone 1800 500 880).

Before you use it

When you must not use it

Do not use BIMTOP eye drops if:

- you have an allergy to bimatoprost or any of the ingredients listed at the end of this leaflet
- the seal around the cap is broken
- the bottle/package shows signs of tampering
- the product does not look quite right
- the expiry date on the bottle has passed.

If you use this medicine after the expiry date has passed, it may not work effectively.

Do not put the eye drops into your eye(s) while you are wearing soft contact lenses.

The preservative in BIMTOP eye drops (benzalkonium chloride) may be deposited in soft contact lenses. You can put your soft contact lenses back into your eyes 15 minutes after you have used BIMTOP eye drops.

It is not known if BIMTOP eye drops are safe and useful for children and adolescents under 18 years.

These drops are for topical use only.

Before you start to use it

Tell your doctor if:

1. you have had an allergy to any medicines or any other substances, such as foods, preservatives or dyes.
2. you have breathing problems.
3. you have liver or kidney problems.
4. you have low blood pressure or heart rate.
5. you have a disease causing swelling of the back of the eye.

6. you have an inflammatory eye condition.
7. you are pregnant or intend to become pregnant. Like most medicines, BIMTOP eye drops should not be used during pregnancy unless clearly necessary.
8. you are breast-feeding or intend to breast-feed.

Before you start using BIMTOP eye drops your doctor should tell you that some changes to your eyes may occur which may be permanent.

Eyelashes may grow longer and thicker, and eyelashes, the skin around the eye and the coloured part of the eye may become darker. If only one eye is being treated the cosmetic differences between the eyes may be noticeable. None of these changes affect vision.

If you have any concerns, ask your doctor or pharmacist.

Hair may grow where BIMTOP contacts the skin. It is important to use as directed.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

It is not expected that this medicine will interact with other medicines, however you should always ask your optical practitioner, doctor or pharmacist if you have any concerns about using BIMTOP eye drops as well as other medications.

There is a potential for the eye pressure effect to be reduced if using other glaucoma eye drops of the same type as BIMTOP.

How to use it

How much to use

Use BIMTOP eye drops only as prescribed by your doctor.

Your doctor will tell you how many drops you need to use each day.

The usual dose is one drop in the affected eye(s) once daily, given in the evening.

Follow all directions given to you by your doctor carefully.

The directions may differ from the information contained in this leaflet.

Use BIMTOP eye drops every day, at about the same time each day, unless your doctor tells you otherwise.

Using your eye drops at the same time each day will have the best effect on your eye pressure. It will also help you remember when to use the eye drops.

If you are using more than one eye drop product, wait 5 minutes before using the second product.

If you are being changed from one eye drop to another, follow your doctor's instructions carefully as to when to stop the old drops and when to start the new drops.

How to use it

You may find it easier to put drops in your eye while you are sitting or lying down.

If you are wearing soft contact lenses, remove them before putting the drops in your eye.

To open a new bottle of BIMTOP eye drops first tear off the protective seal from the bottle. The contents are sterile if the seal is intact.

The seal will break and you can pull it off and then throw it away.

1. Wash your hands well with soap and water.
2. Remove the lid/cap.
3. Hold the bottle upside down in one hand between your thumb and forefinger or index finger.
4. Using your other hand, gently pull down your lower eyelid to form a pouch or pocket.
5. Tilt your head back and look up.

6. Put the tip of the bottle close to your lower eyelid. Do not let it touch your eye.
7. Release one drop into the pouch or pocket formed between your eye and eyelid by gently squeezing the bottle.
8. Close your eye. Do not blink or rub your eye.
9. While your eye is closed, place your index finger against the inside corner of your eye and press against your nose for about two minutes. This will help to stop the medicine from draining through the tear duct to the nose and throat, from where it can be absorbed into other parts of your body. Ask your doctor for more specific instructions on this technique.
10. Replace the lid/cap, sealing it tightly.
11. Wash your hands again with soap and water to remove any residue.

Wait 15 minutes before replacing your contact lenses.

Be careful not to touch the dropper tip against your eye, eyelid or anything else to avoid contaminating the eye drops.

How long to use it

BIMTOP eye drops help control your condition, but do not cure it. Therefore, it must be used every day.

Continue using BIMTOP eye drops for as long as your doctor prescribes.

If you forget to use it

If it is almost time for your next dose, skip the dose you missed and use your next dose when you are meant to. Otherwise, use the drops as soon as you remember, and then go back to using them as you would normally.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

Do not use double the amount to make up for the dose that you missed.

If you take too much (overdose)

If you accidentally put several drops in your eye(s), immediately rinse your eye(s) with warm water.

If you think that you or anyone else may have swallowed any or all of the contents of a bottle of BIMTOP eye drops, immediately telephone your doctor or Poisons Information Centre (Australia: telephone 13 11 26) for advice, or go to casualty at your nearest hospital. Do this even if there are no signs of discomfort or poisoning.

While you are using it

Things you must do

Have your eye pressure checked when your eye specialist says, to make sure BIMTOP eye drops are working.

If you develop an eye infection, receive an eye injury or have eye surgery tell your doctor.

Your doctor may tell you to use a new container of BIMTOP eye drops because of possible contamination of the old one.

If you become pregnant while using BIMTOP eye drops tell your doctor immediately.

If you wear soft contact lenses, remove them before using BIMTOP eye drops. Leave your lenses out for at least 15 minutes after putting in the eye drops.

Tell your doctor if your condition gets worse or does not get better while using BIMTOP eye drops.

If you are about to start any new medicine tell your doctor and pharmacist that you are using BIMTOP eye drops.

Things you must not do

Do not give it to anyone else, even if they have the same condition as you.

Do not stop using this medicine without first talking to your doctor.

If you stop using your eye drops, your eye pressure may rise again and damage to your eye may occur.

Things to be careful of

Your vision may blur for a short time after you put in your BIMTOP eye drops. If this happens you should wait until you can see well again before you drive or use machinery.

BIMTOP eye drops are not expected to cause any problems with your ability to drive a car or operate machinery. However, as a general precaution be careful driving or operating machinery until you know how it affects you.

Side effects

Tell your optical practitioner, doctor or pharmacist as soon as possible if you do not feel well while you are using BIMTOP eye drops.

Check with your doctor as soon as possible if you have any problems while using this medicine, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Ask your optical practitioner, doctor or pharmacist any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- red, congested eyes
- growth of eyelashes
- itching or irritation of eye/s

Less often the following effects have been seen:

- other eye-related effects such as discharge from the eye, eye

discomfort, eye itchiness, redness in or around the eye, increased tears and inflamed areas around eye/s, small lesions or erosions on the eye surface, allergic effects on eye and surrounding eyelid, deepened eyelids, pain in the eye, feeling of something in the eye, burning of eye and nearby eyelid, dryness, irritation, sensitivity to light, an increase in colouring or pigment of area around eye, blurred vision, visual changes, eyelash darkening, darkening of the coloured part of the eye, swelling of the back of the eye.

Rarely:

Other eye related problems can occur such as spasm of the eye where there is uncontrolled blinking and squeezing of eyelid, swelling of eyelid, inflammation of the coloured part of eye, bleeding in eye chamber, eyelid retraction.

There can also be effects on the body as a whole such as headache, weakness, and very rarely dizziness, depression, infection, nausea, high blood pressure, skin pigmentation, asthma, exacerbation of asthma, shortness of breath and abnormal hair growth.

Other side effects not listed above may also occur in some people.

After using it

Storage

Keep your BIMTOP eye drops in a cool place where the temperature stays below 25°C.

Keep the bottle where children cannot reach it.

Do not leave the top/lid off the bottle for any length of time to avoid contaminating the eye drops.

Disposal

Throw out any remaining solution after four weeks from the date of opening.

Eye drops contain a preservative which helps prevent germs growing in the solution for the first four weeks after opening the bottle. After this time there is a greater risk that the drops may become contaminated and cause an eye infection. A new bottle should be opened.

If your doctor tells you to stop using the eye drops or they have passed their expiry date, ask your pharmacist what to do with any remaining solution.

Product description

What it looks like

BIMTOP eye drops are a clear, colourless, sterile solution.

Ingredients

Active ingredient:

bimatoprost 0.3mg/mL

Preservative:

Benzalkonium chloride

Inactive ingredients:

- sodium phosphate dibasic
- sodium chloride
- citric acid monohydrate
- sodium hydroxide and/or hydrochloric acid may be added to adjust pH
- purified water.

Sponsor

Aspen Pharma Pty Ltd

34-36 Chandos Street

St Leonards NSW 2065

Australia.

Australian registration number:

AUST R 274754

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