

BIMTOP®

bimatoprost

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 is 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 this medicine has 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 BIMTOP

When you must not use it

Do not use BIMTOP if you have an allergy to:

- any medicine containing bimatoprost
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

These drops are for topical use only.

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.

Do not give this medicine to a child under the age of 18 years.

Safety and effectiveness in children younger than 18 years have not been established.

Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start using this medicine, talk to your doctor.

Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- you have breathing problems
- you have liver or kidney problems
- you have low blood pressure or heart rate
- you have a disease causing swelling of the back of the eye
- you have an inflammatory eye condition

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Your doctor can discuss with you the risks and benefits involved.

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

During treatment, BIMTOP may cause a loss of fat around the eye, which may cause your eyelid crease to deepen, your eye to appear sunken, your upper eyelid to droop, the skin around your eye to tighten and the lower white part of your eye to become more visible. The changes are typically mild, but if pronounced, they can affect your field of vision. The changes may disappear if you stop taking BIMTOP.

Eyelashes may also 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.

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

If you have not told your doctor about any of the above, tell them before you start taking BIMTOP.

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.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to use BIMTOP

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

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, they must be used every day.

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

If you forget to use it

If you miss a dose, skip the dose you missed and administer 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 administer a double dose 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 Accident and Emergency at the nearest hospital. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using BIMTOP

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.

This medicine helps most people with glaucoma, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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

More often the following effects have been seen:

- loss of fat in the eye region which can lead to deepening of your eyelid crease
- sunken eye
- drooping eyelid
- tightening of the skin around your eye
- lower white part of your eye to become more visible.

The above list includes the more common side effects of your medicine.

Less often the following effects have been seen:

- 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

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- 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
- headache, weakness, and dizziness
- hypersensitivity
- depression
- signs of infection such as pus or foul smells exuding from the eye(s)
- nausea
- skin pigmentation
- asthma, exacerbation of asthma, or shortness of breath
- abnormal hair growth

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

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

After using BIMTOP

Storage

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

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

Do not store BIMTOP or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

Write the date on the bottle when you open the eye drops, and dispose of any remaining solution after four weeks.

Open a new bottle every four weeks.

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.

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

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

Ingredients

BIMTOP contains 300 micrograms/mL of bimatoprost as the active ingredient.

The eye drops also contain the following inactive ingredients:

- benzalkonium chloride
- citric acid monohydrate
- dibasic sodium phosphate
- hydrochloric acid
- sodium chloride
- sodium hydroxide
- water for injections

Distributor

BIMTOP is distributed in Australia by:

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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