Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Bimprozt. 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 Bimprozt against the benefits it is expected to 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 Bimprozt is used for

Bimprozt is 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.

Bimprozt lowers the pressure in the eye by helping the flow of fluid out of the eye chamber.

Bimprozt can be used alone or together with other medicines to lower raised pressure within your eyes.

Although Bimprozt helps control your glaucoma it does not cure it. So you must keep using it until your doctor tells you to

Your doctor may have prescribed Bimprozt for another reason.

Ask your doctor if you have any questions about why Bimprozt has been prescribed for you.

Bimprozt is only available with a doctor's prescription from pharmacies.
Bimprozt is not addictive.

Before you use Bimprozt

When you must not use it

Do not use Bimprozt if you have an allergy to bimatoprost or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include:

asthma, wheezing or shortness of breath

- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- · hives, itching or skin rash
- fainting

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

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

Do not use Bimprozt if the:

- seal around the cap is broken
- bottle/packaging shows signs of tampering
- · product does not look quite right
- expiry date on the bottle has passed. If you use this medicine after the expiry date has passed, it may not work effectively.

It is not known if Bimprozt is safe or effective for children and adolescents under 18 years of age.

These drops are for application to the eye(s) only.

If you are not sure whether you should start using Bimprozt, talk to your doctor. Before you start to take it

Tell your doctor if you have:

- an allergy to any other medicines or any other substances, such as foods, preservatives or dyes
- any breathing problems
- · liver or kidney problems
- low blood pressure or heart rate
- a disease causing swelling of the back of the eye
- · an inflammatory eye condition.

Tell your doctor if you are pregnant or intend to become pregnant

Like most medicines, Bimprozt should not be used during pregnancy, unless clearly necessary.

Tell your doctor if you are breast-feeding or intend to breast-feed.

It is not known if bimatoprost passes into human milk. Your doctor will discuss the risks involved with using Bimprozt when breastfeeding.

If you have not told your doctor about any of the above, tell him or her before you use Bimprozt.

Before you start using Bimprozt, your doctor should tell you that some changes to your eyes may occur which may be permanent.

During treatment, Bimprozt 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 using Bimprozt.

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 noticable. None of these changes affect vision. If you have any concerns, ask your doctor or pharmacist.

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

Taking other medicines

Tell your doctor or pharmacist 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 Bimprozt will interact with other medicines, however you should always ask your optical practitioner, doctor or pharmacist if you have any concerns about using Bimprozt 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 Bimprozt.

How to use Bimprozt

How much to use

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

Use Bimprozt only as prescribed by your doctor.

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

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

Use Bimprozt every day, at about the same times 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(s).

To open a new bottle of Bimprozt, 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.

Instructions:

- Wash your hands well with soap and water.
- Twist off the protective overcap from the bottle.
- Place the cap upside down on a flat surface. Do not touch the inside of the cap. This will help keep the inside of the cap clean and keep germs out of the eye drops.

- 4. Hold the bottle upside down in one hand between your thumb and index finger.
- Using your other hand, gently pull down the lower eyelid of your affected eye to form a pouch.
- 6. Tilt your head back and look up.
- Put the tip of the bottle close to your lower eyelid. Do not let it touch your eye.
- Squeeze the bottle gently so that only one drop goes into the pouch formed between your eye and eyelid, then release the lower eyelid.
- Close your eye and keep it closed. Do not blink or rub your eye.
- 10. While your eye is still 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.
- 11. Repeat steps 4 to 10 with the other eye if instructed to do so by your doctor.
- Replace the cap on the bottle, sealing it tightly. Do not overtighten the cap as you may damage the bottle and cap.
- 13. Wash your hands again with soap and water to remove any residue.

Wait at least 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.

Contaminated eye drops may give you an eye infection.

How long to use it

Continue using Bimprozt every day for as long as your doctor prescribes.

Bimprozt helps control your condition but does not cure it.

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 have trouble remembering to use your eye drops, ask your pharmacist for some hints.

If you use too much (overdose)

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

If you think that you or anyone else may have swallowed Bimprozt, or used too many drops, immediately telephone your doctor or the Australian Poisons Information Centre (telephone 131 126) for advice, or go to the Accident and Emergency Department at your nearest hospital. Do this even if there are no signs of discomfort or poisoning.

While you are using Bimprozt

Things you must do

Have your eye pressure checked when your eye specialist says, to make sure Bimprozt is working for you.

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 bottle of Bimprozt because of possible contamination of the old one, or may advise you to stop your treatment with Bimprozt.

If you become pregnant while using Bimprozt tell your doctor immediately.

If you wear soft contact lenses remove them before using Bimprozt. 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 Bimprozt.

If you are about to be started on any new medicine tell your doctor and pharmacist that you are using Bimprozt.

Things you must not do

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

Do not stop using Bimprozt without first talking to your doctor.

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

Things to be careful of

Be careful driving or operating machinery until you know how Bimprozt affects you.

Bimprozt generally does not cause any problems with your ability to drive a car or operate machinery. However, it may cause blurred vision in some people. Make sure you know how you react to Bimprozt and that your vision is clear before driving a car or operating machinery.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while using Bimprozt.

Bimprozt helps most people with high eye pressure and 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 treatment if you get some of the side effects.

Ask your optical practitioner, doctor or pharmacist to answer 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, and the lower white part of your eye to become more visible.

Less often the following effects have been seen:

other eye-related effects such as discharge from the eye, eye discomfort, eve 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, deepened eyelid sulcus (sockets sunken), eyelid retraction.

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

Tell your doctor if you notice any other effects.

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

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After using Bimprozt

Storage

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

Do not store Bimprozt or any other medicine in the bathroom or near a sink. Do not leave it in the car or on window sills. Do not carry the eye drops in pockets of your clothes.

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.

Put the top back on the bottle right away after use to avoid contaminating the eye drops.

Disposal

Write the date on the bottle when you open the eye drops and throw out 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 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

Bimprozt comes in plastic bottles, each containing 3 mL of clear colourless, sterile eye drop solution.

Ingredients

Active ingredient:

Bimatoprost 300 microgram/ml

Preservative:

Benzalkonium chloride

Inactive ingredients:

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

Name and Address of the Sponsor

Arrotex Pharmaceuticals Pty Ltd 15 – 17 Chapel Street Cremorne VIC 3121 www.arrotex.com.au

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