

Approved Patient Information Leaflet for Medicines for Human Use:

BIMAPRES FORT

SCHEDULING STATUS: S4

BIMAPRES FORT, eye drops, solution

Bimatoprost 0,3 mg/mL and timolol 5,0 mg/mL

Read all of this leaflet carefully before you start using BIMAPRES FORT

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- BIMAPRES FORT 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 FORT is and what it is used for
2. What you need to know before you use BIMAPRES FORT
3. How to use BIMAPRES FORT
4. Possible side effects
5. How to store BIMAPRES FORT
6. Contents of the pack and other information

1. What BIMAPRES FORT is and what it is used for

The active ingredients in BIMAPRES FORT are bimatoprost and timolol.

BIMAPRES FORT contains two different active substances (bimatoprost and timolol) that both reduce pressure in the eye. Bimatoprost belongs to a group of medicines called prostamides, a prostaglandin analogue. Timolol belongs to a group of medicines called beta-blockers.

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 and could eventually damage your sight (an illness called glaucoma).

BIMAPRES FORT works by reducing the production of liquid and also increasing the amount of liquid that is drained. This reduces the pressure inside the eye.

BIMAPRES FORT eye drops are used to treat high pressure in the eye in adults, including the elderly. This high pressure can lead to glaucoma. Your doctor will prescribe you BIMAPRES FORT when other eye drops containing beta-blockers or prostaglandin analogues have not worked sufficiently on their own.

2. What you need to know before you use BIMAPRES FORT

Do not use BIMAPRES FORT

- if you are hypersensitive (allergic) to bimatoprost, timolol, beta-blockers or any of the other ingredients of BIMAPRES FORT (listed in section 6)
- if you have now or have had in the past respiratory problems such as asthma, severe chronic obstructive bronchitis (severe lung disease which may cause wheeziness, difficulty in breathing and/or long-standing cough)
- if you have heart problems such as low heart rate, heart block or heart failure.

Warnings and precautions

Take special care with BIMAPRES FORT if you have now or have had in the past:

- coronary heart disease (symptoms can include chest pain or tightness, breathlessness or choking), disturbances of heart rate such as slow heartbeat
- disturbances of heart rate such as slow heartbeat
- breathing problems, asthma or chronic obstructive pulmonary disease
- poor blood circulation disease (such as Raynaud's disease or Raynaud's syndrome)
- overactivity of the thyroid gland as timolol may mask signs and symptoms of thyroid disease
- diabetes, as timolol may mask signs and symptoms of low blood sugar
- severe allergic reactions
- liver or kidney problems
- eye surface problems
- separation of one of the layers within the eyeball after surgery to reduce the pressure in the eye
- known risk factors for macular oedema (swelling of the retina within the eye leading to worsening vision), for example, cataract surgery.

Tell your doctor before surgical anaesthesia that you are using BIMAPRES FORT, as timolol may change effects of some medicines used during anaesthesia.

BIMAPRES FORT may cause your eyelashes to darken and grow and cause 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.

Children and adolescents

BIMAPRES FORT should not be used in children and teenagers under 18 years of age.

Other medicines and BIMAPRES FORT

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

BIMAPRES FORT can affect or be affected by other medicines you are using, including others for the treatment of glaucoma. Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Tell your doctor if you are using or intend to use:

- medicines to lower blood pressure
- heart medicine
- medicines to treat diabetes
- quinidine (used to treat heart conditions and some types of malaria)
- medicines to treat depression known as fluoxetine and paroxetine
- another eye medicine to treat glaucoma or high eye pressure.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before using BIMAPRES FORT.

BIMAPRES FORT should not be used during pregnancy.

Do not use BIMAPRES FORT if you are breastfeeding your baby. Timolol may get into your breast milk. Ask your doctor for advice before taking any medicine if you are breastfeeding.

Driving and using machines

BIMAPRES FORT may cause blurred vision. Do not drive or use machinery until the symptoms have cleared.

BIMAPRES FORT contains benzalkonium chloride

This medicine contains 0,05 mg benzalkonium chloride (a preservative) in each 1 mL of solution which is equivalent to 0,005 % (*m/v*).

Do not use the drops when you are wearing your contact 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 FORT

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

Always use BIMAPRES FORT exactly as your doctor has instructed you. Check with your doctor or pharmacist if you are not sure.

The usual dose is one drop of BIMAPRES FORT in each eye that needs treatment, once every day, either in the morning or in the evening, following the instructions for use below (see “Instructions for use”).

Use BIMAPRES FORT at the same time each day.

Duration of administration

Your doctor will tell you how long your treatment with BIMAPRES FORT will last.

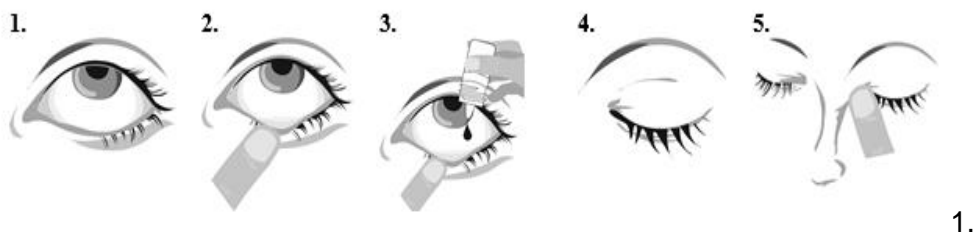
Do not stop treatment early. If you have the impression that the effect of BIMAPRES FORT is too strong or too weak, tell your doctor or pharmacist.

Method of administration

BIMAPRES FORT should only be applied to the eye.

If you use BIMAPRES FORT with another eye medicine, wait at least five minutes between using BIMAPRES FORT and the other eye medicine. Use any eye ointment or gel last.

Instructions for use



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.
5. Whilst keeping the eye closed, press your finger against the corner of the closed eye (the site where the eye meets the nose) and hold for 2 minutes. This helps to stop BIMAPRES FORT getting into the rest of the body.

If a drop misses your eye, try again.

Wipe off any excess that runs down the cheek.

If you wear contact lenses, take your lenses out before using this medicine. Wait 15 minutes after using the drops, and before you put your lenses back in.

To avoid contamination (dirtying) the solution and 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 take more BIMAPRES FORT than you should

If you use more BIMAPRES FORT 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.

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

If you forget to take BIMAPRES FORT

Do not take a double dose to make up for forgotten individual doses.

If you have missed one daily dose of BIMAPRES FORT, you should not take the missed dose later that day when you remember, but you should continue with the next dose the next day.

You should not use more than one drop in the affected eye(s) daily.

If you stop using BIMAPRES FORT

BIMAPRES FORT should be used every day to work properly. If you stop using BIMAPRES FORT the pressure inside your eye may go up, therefore do not stop using BIMAPRES FORT without speaking to your doctor.

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

4. Possible side effects

BIMAPRES FORT can have side effects.

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- shortness of breath or difficulty breathing.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects

Affecting the eye

- eye redness
- longer eyelashes
- burning, itching, stinging of the eye
- sensitivity to light
- eye pain
- sticky eyes
- dry eyes
- a feeling of something in the eye
- small breaks in the surface of the eye with or without inflammation
- difficulty in seeing clearly
- redness and itching of the eyelids
- darkening of the eyelids
- excessive tearing
- darker skin colour around the eyes

Less frequent side effects

Affecting the eye

- inflammation of the iris (coloured part of the eye)
- eye irritation
- swollen conjunctiva (see-through layer of the eye)
- watery eyes
- swollen or painful eyelids
- reduced vision
- tired eyes
- in-growing eyelashes

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- darker iris colour
- eyes appearing sunken
- the upper or lower eyelid margins are drawn back from the normal position
- darkening of the eyelashes

Affecting the body

- headache
- runny nose, sneezing, and stuffiness
- unwanted male-pattern hair growth on a woman's face, chest and back

Side effects with frequency unknown

Affecting the eye

- cystoid macular oedema (swelling of the retina within the eye leading to worsening of vision)
- eye swelling
- blurred vision
- eye discomfort

Affecting the body

- allergies including skin allergy and eye allergy
- difficulty sleeping
- nightmares
- changes in your taste sensation
- dizziness
- slow heart rate
- high blood pressure
- asthma

- hair loss
- discolouring of skin around the eyes
- tiredness.

Additional side effects have been seen in patients using eye drops containing timolol or bimatoprost and so may possibly be seen with BIMAPRES FORT. Like other medicines applied into eyes, timolol is absorbed into the blood. This may cause similar side effects as seen with "intravenous" and /or "oral" beta-blocking agents. The chance of having side effects after using eye drops is lower than when medicines are for example, taken by mouth or injected. Listed side effects include reactions seen within bimatoprost and timolol when used for treating eye conditions:

- infection (primarily colds and upper respiratory symptoms)
- severe allergic reactions with swelling and difficulty breathing which could be life-threatening
- allergic skin reactions (including rash, itching, hives)
- low blood sugar
- behavioural changes and psychic disturbances including anxiety, confusion, depression; disorientation, hallucination, nervousness, drowsiness, memory loss
- fainting; stroke; decreased blood flow to the brain; worsening of myasthenia gravis (increased muscle weakness); tingling sensation
- decreased sensation of your eye surface; double vision; drooping eyelid; separation of one of the layers within the eyeball after surgery to reduce the pressure in the eye; changes in your eye's ability to clearly focus the images you are seeing (due to withdrawal of miotic therapy in some cases); inflammation of the front surface of the eye (keratitis), bleeding in the back of

the eye (retinal bleeding), inflammation within the eye, increased blinking or eye movements that you cannot control

- ringing or buzzing noises in one or both of your ears
- heart failure; irregularity or stopping of the heartbeat; slow or fast heartbeat; too much fluid, mainly water, accumulating in the body; chest pain and worsening of severe pain in the chest, often also spreading to the shoulders, arms, and neck, owing to an inadequate blood supply to the heart (angina pectoris)
- low blood pressure, pain or cramping in the lower leg caused by inadequate blood flow to the muscles, swelling or coldness of your hands, feet and extremities, caused by constriction of your blood vessels
- difficulty breathing; wheezing; cough, inflamed and stuffed up nasal passages, irritation and swelling of the upper airways, worsening of asthma, worsening of the lung disease called chronic obstructive pulmonary disease (COPD)
- diarrhoea; stomach pain; feeling and being sick; indigestion; dry mouth, an eating disorder causing you to obsess about your weight and what you eat (anorexia)
- red scaly patches on skin; skin rash, abnormal hair growth
- muscle pain, an inflammatory disease caused when the immune system attacks its own tissues (systemic lupus erythematosus)
- reduced sexual urge; sexual dysfunction, fibrous scar tissue inside the penis that causes curved, painful erections, inflammation and extensive scar tissue (fibrosis) occur in the back of the abdominal cavity, behind the membrane that surrounds the organs of the digestive system
- weakness, swelling of your lower legs or hands
- 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 doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. 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 FORT.

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 FORT

- 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

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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 FORT contains

The active substances are bimatoprost and timolol.

One mL of solution contains 0,3 mg bimatoprost and 5 mg timolol.

The other ingredients are

Benzalkonium chloride (preservative)

Citric acid monohydrate

Dibasic sodium phosphate heptahydrate

Sodium chloride

Sodium hydroxide or hydrochloric acid (for pH-adjustment)

What BIMAPRES FORT looks like and contents of the pack

BIMAPRES FORT is a colourless solution that is a practically clear and free of particles.

BIMAPRES FORT eye drops, 3 mL solution is filled in a 5 mL white LDPE bottles with dark blue, tamper-proof HDPE screw cap and white LDPE dropper insert.

The closed bottles are packed into folding carton together with the leaflet.

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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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This leaflet was last revised in

03 October 2023

Registration number

54/15.4/0322.321

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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