Consumer Medicine Information (CMI) summary

The <u>full CMI</u> on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using GANFORT[®] 0.3/5 eye drops?

GANFORT^{*} 0.3/5 eye drops contains the active ingredients bimatoprost and timolol (as maleate). GANFORT^{*} 0.3/5 eye drops are used to lower raised pressure in the eye and to treat glaucoma.

For more information, see Section <u>1. Why am I using GANFORT® 0.3/5 eye drops?</u> in the full CMI.

2. What should I know before I use GANFORT[®] 0.3/5 eye drops?

Check the list of ingredients at the end of the CMI. Do not use GANFORT^{*} 0.3/5 eye drops if you have ever had an allergic reaction to any of them.

Talk to your doctor before you use this medicine if he/she is not aware that you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use GANFORT® 0.3/5 eye drops? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with GANFORT^{*} 0.3/5 eye drops and affect how it works, or GANFORT^{*} 0.3/5 eye drops may interfere with other medicines and affect how they work.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use GANFORT[®] 0.3/5 eye drops?

- Use one drop in your affected eye(s), according to your doctor's instructions.
- Use the drops each morning.
- Please refer to the full instructions which can be found in Section <u>4. How do I use GANFORT® 0.3/5 eye drops?</u> in the full CMI.

5. What should I know while using GANFORT[®] 0.3/5 eye drops?

Things you should do	 Remind any doctor, dentist, pharmacist, or optometrist you visit that you are using GANFORT[*] 0.3/5 eye drops. Continue to use GANFORT[*] 0.3/5 eye drops every day unless your doctor tells you to stop.
	 GANFORT[*] 0.3/5 eye drops helps to control your condition but does not cure it. Keep all your appointments so your condition can be checked.
Things you should not do	 Do not touch the dropper tip against your eye, eye lid or any surface Do not stop using GANFORT* 0.3/5 eye drops without checking with your doctor. Do not use GANFORT* 0.3/5 eye drops while you are wearing contact lenses.
Driving or using machines	 Wait until your vision clears after using GANFORT[*] 0.3/5 eye drops before driving or using machines.
Drinking alcohol	• There is no information on the effects of using GANFORT [®] 0.3/5 eye drops with alcohol.
Looking after your medicine	 Follow all instructions on the carton Store it in a cool dry place, below 25°C, away from moisture, heat, or sunlight.

For more information, see Section 5. What should I know while using GANFORT® 0.3/5 eye drops? in the full CMI.

6. Are there any side effects?

The most common side effects include red, congested eyes, or growth of eyelashes. Note that side effects can occur in other parts of the body, including serious effects on the heart or, blood vessels, decreased blood flow to the brain, serious allergic reaction (anaphylaxis).For more information, including what to do if you have any side effects, see Section <u>6. Are there any side effects</u>? in the full CMI.

GANFORT[®] 0.3/5 eye drops (gan-fort)

Active ingredients: bimatoprost & timolol (bim-at-oh-prost & tim-oh-lol)

Consumer Medicine Information (CMI)

This leaflet provides important information about using GANFORT^{*} 0.3/5 eye drops. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using GANFORT^{*} 0.3/5 eye drops.

Where to find information in this leaflet:

1. Why am I using GANFORT® 0.3/5 eye drops?

2. What should I know before I use GANFORT[®] 0.3/5 eye drops?

3. What if I am taking other medicines?

4. How do I use GANFORT[®] 0.3/5 eye drops?

5. What should I know while using GANFORT® 0.3/5 eye drops?

- 6. Are there any side effects?
- 7. Product details

1. Why am I using GANFORT[®] 0.3/5 eye drops?

GANFORT^{*} 0.3/5 eye drops contain the active ingredients bimatoprost and timolol (as maleate).

GANFORT^{*} 0.3/5 eye drops are used to lower raised pressure in the eye and to treat glaucoma. It works by decreasing the production of fluid in the eye and by helping the flow of fluid out of the eye.

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.

Although GANFORT^{*} 0.3/5 eye drops help control your condition, they will not cure it.

Your doctor may have prescribed this medication for another reason. Ask your doctor if you have any questions

about why GANFORT[®] 0.3/5 eye drops have been prescribed for you.

2. What should I know before I use GANFORT[®] 0.3/5 eye drops?

Warnings

Do not use GANFORT[®] 0.3/5 eye drops if:

- you are allergic to bimatoprost or timolol, or any of the ingredients listed at the end of this leaflet.
- you have or have had any problems with your lungs, such as asthma, bronchospasm, or a condition called chronic obstructive pulmonary disease (COPD).
- you have or have had a heart condition, such as a slow heartbeat, irregular heartbeat, or heart failure.
- The seal around the cap is broken, the bottle/packaging shows signs of tampering, or the product does not look quite right.

Check with your doctor if:

- your eye(s) is/are inflamed
- you have fluid build-up in the light-sensitive layer at the back of the eye, known as the macula
- you have had eye surgery
- you have a diabetes-related eye condition, such as diabetic retinopathy or blockage of a retinal vein
- your eye does not have a lens or your eye has an artificial lens, following cataract surgery
- the capsule ("bag") that normally holds the eye's lens in place is torn, or ruptured
- you have had severe allergic reactions (anaphylaxis) to such things as medicines, foods, dyes
- you have angina or other problems with your heart or blood vessels
- you have low blood pressure
- you have or have had problems with your liver or kidneys
- you have an overactive thyroid
- you have diabetes
- you are about to have surgery under general anaesthetic
- you have muscle weakness
- you have problems with your circulation, such as Raynaud's syndrome
- you have any disease that affects the surface of the eye (cornea)
- you take any medicines for any other condition.
- you have had an allergy to any medicines or any other substances, such as foods, preservatives or dyes

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and

how to monitor for them. See additional information under Section <u>6. Are there any side effects</u>?

Pregnancy and breastfeeding

Make sure your doctor is aware that you are pregnant or plan to become pregnant or are breastfeeding or intend to breastfeed.

Cosmetic effects

Before you start using GANFORT[®] 0.3/5 eye drops your doctor should tell you that some changes to your eyes may occur which may be permanent.

During treatment, GANFORT^{*} 0.3/5 eye drops 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 GANFORT^{*} 0.3/5 eye drops.

Eyelashes may also grow longer and thicker, and eyelashes, the skin around the eye and the coloured part of the eye (iris) 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 GANFORT^{*} 0.3/5 eye drops contact the skin. It is important to use as directed.

3. What if I am taking other medicines?

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

Some medicines may interfere with GANFORT^{*} 0.3/5 eye drops and affect how it works, while GANFORT^{*} 0.3/5 eye drops may affect how other medicines work.

Medicines where GANFORT^{*} 0.3/5 eye drops may <u>increase</u> their effect include:

- medicines for high blood pressure
- some medicines used to treat diabetes
- some medicines used to treat heart conditions, such as for irregular heart beats
- medicines used to expand blood vessels (vasodilator drugs).
- medicines to treat depression

These medicines may be affected by GANFORT^{*} 0.3/5 eye drops, or affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect GANFORT^{*} 0.3/5 eye drops.

4. How do I use GANFORT[®] 0.3/5 eye drops?

Follow all directions given to you by your doctor carefully. The directions may differ from the information contained in this leaflet.

How much to use

- Your doctor will tell you how many drops you need to use each day. Use GANFORT^{*} 0.3/5 eye drops only as prescribed by your doctor.
- The usual dose of GANFORT^{*} 0.3/5 is one drop in your affected eye(s), according to your doctor's instructions.

When to use GANFORT[®] 0.3/5 eye drops

Use the drops each morning.

Use GANFORT^{*} 0.3/5 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.

In some instances, GANFORT^{*} 0.3/5 eye drops need to be used with other eye drops. Your doctor will let you know which drops, how to use them, and how long to use them.

Wait at least 5 to 10 minutes after using GANFORT^{*} 0.3/5 eye drops before using other eye drops. If you are also using an eye ointment, instill the eye ointment last.

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 GANFORT[°] 0.3/5 eye drops

Do not put the eye drops into your eye(s) while you are wearing soft contact lenses. The preservative in GANFORT^{*} 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 GANFORT^{*} eye drops.

These drops are for use in your eyes only.

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

To open a new bottle of GANFORT^{*} 0.3/5 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.

If a drop misses your eye, try again. Wipe off any excess that runs down the cheek.

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.

If you forget to use $\mathsf{GANFORT}^\circ$ 0.3/5 eye drops

It is important that you use GANFORT[®] 0.3/5 eye drops at the same time each day.

If you miss using your drops and it is almost time for your next dose, use GANFORT[®] 0.3/5 eye drops at the usual time the next day.

If you miss using your drops and remember during the day, use the drops as soon as you remember and go back to using them at your usual time the next day.

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

Do not use double the number of drops to make up for the dose you missed.

If you use too much <code>GANFORT</code> $^{\circ}$ 0.3/5 eye drops

Immediately rinse your eyes with warm water.

If GANFORT[®] 0.3/5 eye drops are accidentally swallowed

You should immediately:

- phone the Poisons Information Centre (13 11 26 in Australia or 0800 POISON (0800 764 766) in New Zealand), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there appear to be no signs of discomfort or poisoning.

5. What should I know while using GANFORT® 0.3/5 eye drops?

Things you should do

- Continue to use GANFORT^{*} 0.3/5 eye drops every day unless your doctor tells you to stop. GANFORT^{*} 0.3/5 eye drops help to control your condition but does not cure it.
- Keep all your doctor's appointments so that your condition can be monitored, and your eye pressure can be checked.
- Tell your doctor if you think your condition is not improving while using GANFORT^{*} 0.3/5 eye drops.

Call your doctor straight away if you:

- develop any problems with your eye(s), such as, trauma, change of vision, infection in the eye or eyelid, or have eye surgery.
- become pregnant while using GANFORT[®] 0.3/5 eye drops.

Remind any doctor, dentist, pharmacist or optometrist you visit that you are using GANFORT[®] 0.3/5 eye drops.

Things you should not do

- Do not touch the dropper tip against your eye, eyelid or anything else, to avoid contaminating the eye drops.
- Do not stop using GANFORT^{*} 0.3/5 eye drops without checking with your doctor. Your eye pressure can rise again and may cause damage to your eye.
- Do not give GANFORT^{*} 0.3/5 eye drops to anyone else, even if they have the same condition as you.

Driving or using machines

Your vision may be blurred after using GANFORT[®] 0.3/5 eye drops. Wait until your vision clears before driving or using machines.

Looking after your medicine

Follow the instructions on the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example:

- do not store it in the bathroom or near a sink, or
- do not store it in the car or on window sills.

Ensure the lid is closed tightly after each use.

Keep it where young children cannot reach it.

When to discard your medicine

Discard the bottle 28 days after first opening it.

Getting rid of any unwanted medicine

If your doctor advises that you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date has passed.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Les	ss serious side effects	 muscle pain excessive or abnorm 		
•	ects on the eye(s): red, congested eyes	Speak to your doctor if you have any of	growth in areas whe product repeatedly of contact with the skir	
•	growth of eyelashes darkening of eyelash colour burning and/or stinging in the	these less serious side	Serious side effects	
	eye	effects and they worry	Serious side effects	
•	itching or irritation of the eyes small lesions on the eye surface eye dryness the feeling of having something in the eye or discomfort in the eye watery eyes	you.	 Effects on the eye(s): eye pain discharge from the eye small spots on the eye changes to vision, do macular edema (building) 	
•	redness or swelling in the eye or area around the eye excessive sensitivity to bright light red, swollen, itching eyelids		 at the back of the ey causes vision to becc spasm of the eyelids there is uncontrollec and squeezing of the 	
•	inflamed eyelids		Effects on the body as a	
•	darkening of the coloured part of the eye (iris) darkening of skin around the eye abnormal hair growth misdirected upper or lower eyelashes that turn inward towards the eye 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. decreased sensation to the front		 slow heartbeat shortness of breath asthma or worsening high blood pressure feeling weak and tire nauseous, dizzy depression (low mod of worthlessness) low blood sugar diarrhoea, stomach p vomiting, indigestion red, scaly patches or rash or hair loss. 	
	of the eye		Effects on the body as a	
Efff • • •	ects on the body as a whole headache ringing in the ear symptoms of a cold such as runny nose or nasal congestion cough increased colour or pigment on the face around the eye feeling tired reduced interest in sex or sexual dysfunction		 severe allergic reacting including swelling of tongue, lips and three breathing symptoms suggestive decreased blood flow brain, such as symptoms stroke, fainting, tingly numbness, muscle were chest pain, here slowly or irregularly, pressure 	

Less serious side effects	What to do
• allergic skin reaction (rash,	
itching, hives) and eye allergy	
• changes in your taste sensation	
• dry mouth	
• inability to sleep, nightmares,	
anxiety, confusion,	
hallucinations or memory loss.	
loss of appetite	
muscle pain	
• excessive or abnormal hair	
growth in areas where the	
product repeatedly comes into	
contact with the skin	

Ser	ious side effects	What to do	
Efff • •	ects on the eye(s): eye pain discharge from the eye small spots on the eye surface changes to vision, double vision macular edema (build-up of fluid at the back of the eye, which causes vision to become blurry) spasm of the eyelids where there is uncontrolled blinking and squeezing of the eyelid	Call your doctor straight away, if you notice any of these serious side effects.	
Eff.	ects on the body as a whole: slow heartbeat shortness of breath asthma or worsening of asthma high blood pressure feeling weak and tired, nauseous, dizzy depression (low mood, feelings of worthlessness) low blood sugar diarrhoea, stomach pain, vomiting, indigestion red, scaly patches on the skin, rash or hair loss.		
•	ects on the body as a whole: severe allergic reaction, including swelling of the eye, tongue, lips and throat, difficulty breathing symptoms suggestive of decreased blood flow to the brain, such as symptoms of a stroke, fainting, tingling or numbness, muscle weakness severe chest pain, heart beating slowly or irregularly, low blood pressure	Go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.	

Serious side effects		What to do
•	swelling or coldness in your hands or feet, pain or tiredness in the legs.	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at <u>www.tga.gov.au/reporting-problems</u> in Australia or to <u>https://nzphvc.otago.ac.nz/reporting/</u> in New Zealand. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

Active ingredients (main ingredients)	 bimatoprost 0.3 mg/mL timolol (as maleate) 5.0 mg/mL
Other ingredients (inactive ingredients)	 benzalkonium chloride citric acid monohydrate dibasic sodium phosphate heptahydrate hydrochloric acid sodium chloride sodium hydroxide purified water

Do not take this medicine if you are allergic to any of these ingredients.

What GANFORT[®] 0.3/5 eye drops look like

GANFORT^{*} 0.3/5 eye drops are a sterile, clear to slightly yellow solution. It is supplied in a 3mL bottle which is packed inside a carton. (AUST R 147830).

Who distributes GANFORT[®] 0.3/5 eye drops?

GANFORT[®] 0.3/5 eye drops are distributed in Australia by:

AbbVie Pty Ltd

241 O'Riordan Street

Mascot NSW 2020

Australia

GANFORT[®] 0.3/5 eye drops are distributed in New Zealand by:

AbbVie Limited

6th Floor, 156-158 Victoria St

Wellington, 6011

New Zealand

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