

GANFORT® PF 0.3/5 EYE DROPS

(bimatoprost 0.3 mg per mL and timolol (as maleate) 5.0 mg per mL)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about GANFORT® PF 0.3/5 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 GANFORT® PF 0.3/5 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 GANFORT® PF 0.3/5 eye drops are used for

GANFORT® PF 0.3/5 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.

GANFORT® PF 0.3/5 eye drops lower the pressure in the eye by decreasing the fluid produced and helping the flow of fluid out of the eye chamber.

Although GANFORT® PF 0.3/5 eye drops help control your condition, it does not cure it.

GANFORT® PF 0.3/5 eye drops are only available with a doctor's prescription from pharmacies. Your doctor may have prescribed GANFORT® PF 0.3/5 eye drops for another reason.

Ask your doctor if you have any questions about why GANFORT® PF 0.3/5 eye drops have been prescribed for you.

For more information about glaucoma, contact Glaucoma Australia Inc (telephone 1800 500 880) or Glaucoma NZ (telephone 64 9373 8779).

Before you use GANFORT® PF 0.3/5 eye drops

When you must not use it

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

- you have an allergy to bimatoprost, timolol or any of the ingredients listed at the end of this leaflet.
- you have bronchospasm, bronchial asthma or have a history of bronchial asthma or other lung disease.
- you have heart conditions, such as a very slow heart rate, an irregular heart beat, or heart failure.
- the seal around the cap is broken.
- the packaging shows any signs of tampering.

- the product does not look quite right such as discoloured.
- the expiry date on the packaging has passed.

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

It is not known if GANFORT® PF 0.3/5 eye drops are safe and useful for children and adolescents under 18 years and therefore its use is not recommended.

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 slow or irregular heart rate, coronary heart disease or heart failure.
3. you have a disease affecting your blood vessels.
4. you have a lung disease including asthma and chronic obstructive pulmonary disease (COPD).
5. you have liver or kidney disease.
6. you have diabetes mellitus or an overactive thyroid.
7. you have low blood pressure.
8. you have a disease called myasthenia gravis which can cause muscle weakness or other symptoms common to that disease.
9. you have eye inflammation or eye surface disease.
10. you have had swelling of the retina within the eye.
11. you have separation of one of the layers within the eyeball after surgery to reduce the pressure in the eye.

12. you have had surgery to reduce the pressure in the eye.

13. you are pregnant or intend to become pregnant. Like most medicines, GANFORT® PF 0.3/5 eye drops should not be used during pregnancy, unless the benefits outweigh the risk to the baby.

14. you are breast-feeding or intend to breast-feed. Your baby may absorb this medicine from breast milk and therefore there is a possibility of harm to the baby.

15. you are due to have surgery under general anaesthetic.

Before you start using GANFORT® PF 0.3/5 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. 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.

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.

Some medicines and GANFORT® PF 0.3/5 eye drops may interfere with each other. These include:

- medicines for high blood pressure
- antidiabetic agents
- some drugs prescribed for heart problems/conditions (e.g. digitalis glycosides, anti-arrhythmics and quinidine)
- any drugs used to increase the size of blood vessels (e.g. guanethidine)
- medicines to treat depression.

These medicines may be affected by GANFORT® PF 0.3/5 eye drops, or may affect how well it works. You may need different amounts of your

medicines, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while using GANFORT® PF 0.3/5 eye drops.

How to use GANFORT® PF 0.3/5 eye drops

How much to use

Your doctor will tell you how many drops you need to use each day. Use GANFORT® PF 0.3/5 eye drops only as prescribed by your doctor.

The usual dose of GANFORT® PF 0.3/5 eye drops is one drop in the affected eye(s) once daily, in the morning.

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

Use GANFORT® PF 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.

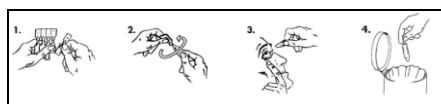
If you are using more than one eye drop product, wait 5 to 10 minutes before using the second product.

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.



Wash your hands well with soap and water before use. Make sure

that the ampoule is intact before use.

1. Tear 1 ampoule from the strip.
2. Hold the ampoule upright (with the cap pointing upwards) and twist off the cap.

3. Gently pull down the lower eyelid to form a pocket. Turn the ampoule upside down and squeeze it to release 1 drop into the affected eye(s).

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.

4. Throw away the ampoule after you have used it, even if there is some solution left.

5. Wash your hands again with soap and water to remove any residue.

The solution should be used immediately after opening.

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 injury and contaminating the eye drops.

How long to use it

GANFORT® PF 0.3/5 eye drops help control your condition, but do not cure it. Therefore, GANFORT® PF 0.3/5 eye drops must be used every day. Continue using GANFORT® PF 0.3/5 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 use 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 an ampoule or ampoules of GANFORT® PF 0.3/5 eye drops, immediately telephone your doctor or **Poisons**

Information Centre (Australia : telephone 13 11 26; New Zealand: telephone 0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at your nearest hospital. Do this even if there are no signs of discomfort or poisoning.

While you are using GANFORT® PF 0.3/5 eye drops

Things you must do

Have your eye pressure checked when your eye specialist says, to make sure GANFORT® PF 0.3/5 eye drops are working.

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

If you become pregnant while using GANFORT® PF 0.3/5 eye drops tell your doctor immediately.

If you wear soft contact lenses, remove them before using GANFORT® PF 0.3/5 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 GANFORT® PF 0.3/5 eye drops.

If you are about to start any new medicine tell your doctor and pharmacist that you are using GANFORT® PF 0.3/5 eye drops.

Things you must not do

Do not give GANFORT® PF 0.3/5 eye drops to anyone else, even if they have the same condition as you.

Do not stop using GANFORT® PF 0.3/5 eye drops 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

Be careful driving or operating machinery until you know how GANFORT® PF 0.3/5 eye drops affect you. GANFORT® PF 0.3/5 eye drops generally should not cause any problems with your ability to drive or operate machinery.

However, GANFORT® PF 0.3/5 eye drops may cause blurred vision/ dizziness/ drowsiness/ tiredness in some people. Make sure you know how you react to GANFORT® PF 0.3/5 eye drops or that your vision is clear before driving or operating machinery.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using GANFORT® PF 0.3/5 eye drops.

GANFORT® PF 0.3/5 eye drops help 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.

Do not be alarmed by this list of possible side effects. You may not experience any of them. Ask your 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 the eyes

- Small lesions or erosions on the eye surface
- Eye dryness
- The feeling of something in the eye(s)
- Watery eyes
- Excessive sensitivity to bright light
- Eye pain
- Red, swollen eyelids
- Swelling of the eye
- Slow heartbeat
- Allergic skin reactions (rash, itching, hives) and eye allergy
- Shortness of breath, wheezing
- Discomfort in the eye
- High blood pressure
- Darkening of the skin around the eye

There can also be effects on the body as a whole such as headache, and an increase in the colouring or pigment in the skin around the eye.

Additional side effects have been seen in patients using GANFORT® 0.3/5 (multidose formulation) and so may possibly be seen with GANFORT® PF 0.3/5 (single dose).

- Superficial damage to the front part of the eye
- Burning and stinging in the eye
- Discharge from the eye
- Visual changes
- Itchy eyelid
- Darkening of the coloured part of the eye
- Eyes appear sunken
- Swelling of the central retina (light-sensitive layer of the eye)

Additional side effects not listed above that have been seen in patients using eye drops containing timolol and so may possibly be seen with GANFORT® PF 0.3/5 eye drops.

These include:

- Severe allergic reactions with swelling and difficulty breathing, which could be life-threatening
- Low blood sugar
- Anxiety, confusion, hallucinations, difficulty sleeping, nightmares, depression, memory loss
- Fainting, stroke, decreased blood flow to the brain, worsening of myasthenia gravis (increased muscle weakness), tingling sensation

- Decreased sensation of the front part of the eye, double vision, drooping eyelid, separation of one of the layers within the eyeball after surgery to reduce the pressure in the eye, irritation and inflammation of the surface of the eye
- Heart failure, irregularity or stopping of the heartbeat, slowing of heart rate, too much fluid, mainly water, accumulating in the body, chest pain
- Low blood pressure, swelling or coldness of your hands and feet, caused by constriction of your blood vessels, pain, discomfort or tiredness in the legs that occurs during walking
- Difficulty breathing, cough, nasal congestion
- Diarrhoea, stomach pain, nausea, vomiting, feeling and being sick, changes in your taste sensation, indigestion, dry mouth
- Red scaly patches on skin, skin rash, hair loss
- Muscle pain
- Reduced sexual urge, sexual dysfunction
- Tiredness
- Ringing in the ears

Other side effects not listed above may also occur in some patients. Additional side effects have been seen in patients using eye drops containing bimatoprost and so may possibly be seen with GANFORT® PF 0.3/5:

These include;

- Allergic reaction in the eye
- Inflammation within the eye
- Redness of the skin surrounding the eye
- Eyelash darkening
- Misdirected upper or lower eyelashes that turn inward towards the eye
- Blurred vision
- Eyelid twitching
- Eyelid has moved away from the surface of the eye,
- Bleeding in the back of the eye (retinal bleeding)
- Uncomfortable and tired eyes
- Red, itchy eyelids
- Inflammation of the coloured part of the eye
- Eyelid swelling
- Decrease in sharpness of vision
- High blood pressure
- Feeling weak

- Infection from colds
- Nausea

Tell your doctor if you notice any other effects.

After using GANFORT® PF 0.3/5 eye drops

Storage

Keep your GANFORT® PF 0.3/5 eye drops in a cool place where the temperature stays below 25°C. Protect from light and moisture. Do not freeze.

Keep the medicine where children cannot reach it.

Disposal

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 ampoules.

Product description

What GANFORT® PF 0.3/5 eye drops look like:

Clear, colourless to slightly yellow sterile solution in a single use ampoule. Contains no antimicrobial agent

Ingredients

Active ingredients:
Bimatoprost 0.3 mg/mL and
Timolol (as maleate) 5.0 mg/mL

Inactive ingredients:
Sodium chloride
Sodium phosphate dibasic
Citric acid monohydrate
Hydrochloric acid and/or
Sodium hydroxide
Purified water

Manufacturer/Supplier

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GANFORT® PF 0.3/5 can be identified by registration number: AUST R 211161

Date of preparation: October 2019

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