

GANFORT® PF EYE DROPS

Consumer Medication Information Leaflet (RiMUP)

bimatoprost (0.3 mg/mL), timolol (5.0 mg/mL) Sterile Ophthalmic Solution

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1. What **GANFORT® PF** is used for

GANFORT® PF is prescribed to reduce high pressure in the eye when other beta blockers or prostaglandin analogues used alone are not enough.

2. How **GANFORT® PF** works

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

3. Before you use **GANFORT® PF**

- When you must not use it

Do not use **GANFORT® PF**:

- if you are allergic (hypersensitive to bimatoprost and timolol, or any of the other ingredients of **GANFORT® PF**. (for a full list of ingredients, see section 8 "PRODUCT DESCRIPTION").
- 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 failure, heart beat disorders (unless controlled by a pacemaker).

- Pregnancy and lactation

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Do not use **GANFORT® PF** if you are pregnant unless your doctor still recommends it.

Do not use **GANFORT® PF** if you are breast-feeding. Timolol may get into your breast milk. Ask your doctor for advice before taking any medicine during breast-feeding.

- Children

GANFORT® PF has only been studied in adults and therefore its use is not recommended in children or adolescents.

- Before you start use it

Take special care with **GANFORT® PF**. Use only if single-use container is intact. Do not touch unit dose tip to eye.

Always use **GANFORT® PF** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Before you use this medicine, tell your doctor if you have now or have had in the past:

- coronary heart disease (symptoms can include chest pain or tightness, breathlessness or choking), heart failure, low blood pressure,
- disturbances of heart rate such as slow heart beat
- breathing problems, asthma or chronic obstructive pulmonary disease
- 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 reaction
- liver problems
- 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 **GANFORT® PF** as timolol may change effects of some medicines used during anaesthesia.

GANFORT® PF may cause your eyelashes to darken and grow, and cause the 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.

- Taking other medicines

GANFORT® PF can affect or be affected by other medicines you are using, including other eye drops for the treatment of glaucoma. If more than one topical eye product is to be used, the different products should be instilled at least 5 minutes apart.

Tell your doctor if you are using or intend to use medicines to lower blood pressure, heart medicine, medicines to treat diabetes.

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

4. How to use **GANFORT® PF**

- How much to use

Recommended dosage in adults (including the elderly):

The recommended dose is one drop of **GANFORT® PF** in the affected eye(s) once daily, either in the morning or in the evening. It should be administered at the same time each day.

Evening dosing may be more effective in eye-pressure lowering than morning dosing. However, consideration should be given to the likelihood of

compliance when considering either morning or evening dosing.

If one dose is missed, treatment should continue with the next dose as planned. The dose should not exceed one drop in the affected eye(s) daily.

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- Instructions for use

Follow these instructions unless the pharmacist or your doctor gave you different advice.

Make sure that the single-dose container is intact before use.

The solution should be used immediately after opening. To avoid contamination, do not let the open-end of the single-dose container touch your eye or anything else. Wash your hands before use.

1. Tear one single-dose container from the strip.



2. Hold the single-dose container upright (with the cap uppermost) and twist off the cap.



3. Gently pull down the lower eyelid to form a pocket. Turn the single-dose container upside down and squeeze it to release one drop into each eye. Blink your eyes a few times.



Do not re-use the single-dose container even if there is some solution left.

4. Let go of the lower lid, and close your eye.



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 **GANFORT® PF** getting into the rest of the body.



If a drop misses your eye, try again.

To avoid contamination, do not let the tip of the single dose container touch your eye or anything else. The unit dose container is for one-time use only; one container is sufficient to treat

both eyes. Any unused solution should be discarded immediately after use.

If you use **GANFORT® PF** with another eye medicine, leave at least 5 minutes between putting in **GANFORT® PF** and the other medicine. Use any eye ointment or eye gel last.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking **GANFORT® PF** for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

If you use more **GANFORT® PF** 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.

5. While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking **GANFORT® PF**.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

To avoid contamination, do not allow the dropper tip to come into contact with any surface.

- Things to be careful of

Driving and using machines:
GANFORT® PF has negligible influence on the ability to drive and use machines. As with any eye treatment, if you experience blurred vision, you should wait until the vision clears before driving or using machinery.

In order to minimize systemic absorption of **GANFORT® PF** eye drops, apply pressure to the tear duct for at least 2 minutes immediately following administration of the drug

6. Side effects

Like all medicines, **GANFORT® PF** can cause side effects, although not everybody gets them. You can usually carry on taking the drops, unless the effects are serious. If you're worried, talk to a doctor or pharmacist. Do not stop using **GANFORT® PF** without speaking to your doctor. The following side effects may be seen with **GANFORT®**

Very common side effects

These may affect more than 1 user in 10
Affecting the eye
redness.

Common side effects

These may affect 1 to 9 users in 100

Affecting the eye

burning, itching, stinging, irritation of the conjunctiva (see-through layer 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, hair growing around the eye, darkening of the eyelids, darker skin colour around the eyes, longer eyelashes, eye irritation, watery eyes, swollen eyelids, reduced vision.

Affecting other parts of the body
runny nose, dizziness, headache

Uncommon side effects

These may affect 1 to 9 users in 1,000

Affecting the eye

abnormal sensation in the eye, iris inflammation, swollen conjunctiva (see-through layer of the eye), painful eyelids, tired eyes, ingrowing eyelashes, darkening of iris colour, eyes appear sunken, eyelid has moved away from the surface of the eye, darkening of eyelashes.

Affecting other parts of the body
shortness of breath.

Side effects where the frequency is not known

Affecting the eye

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

Affecting other parts of the body

difficulty breathing / wheezing, symptoms of allergic reaction (swelling, redness of the eye and rash of the skin), changes in your taste sensation, slowing of heart rate, difficulty sleeping, nightmare, asthma, hair loss, discoloration of the skin around the eye, high blood pressure, tiredness.

Additional side effects have been seen in patients using eye drops containing timolol or bimatoprost and so may possibly be seen with **GANFORT**. 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:

- Severe allergic reactions with swelling and difficulty breathing which could be life-threatening
- Low blood sugar
- Depression; 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; inflammation of the surface of the eye, bleeding in the back of the eye (retinal bleeding), inflammation within the eye, eye discharge, increased blinking
- Heart failure; irregularity or stopping of the heartbeat; slow or fast heartbeat; too much fluid, mainly water, accumulating in the body; chest pain
- Low blood pressure, swelling or coldness of your hands, feet and extremities, caused by constriction of your blood vessels
- Cough, worsening of asthma, worsening of the lung disease called chronic obstructive pulmonary disease (COPD)
- Diarrhoea; stomach pain; feeling and being sick; indigestion; dry mouth
- Red scaly patches on skin; skin rash
- Muscle pain
- Reduced sexual urge; sexual dysfunction
- Weakness
- An increase in blood test results that show how your liver is working
- Deepening of the eyelid sulcus due to loss of fat in the eye region which can lead to sunken eyes, drooping eyelids, and incomplete closure of the eyelids

Other side effects reported with eye drops containing phosphates In very rare cases, 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.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

7. Storage and Disposal of GANFORT® PF

- Storage

Keep the single dose container in the aluminium pouch until use.

Shelf life: 2 years. Prescription Only. Do

not use GANFORT® PF after the expiry date which is stated on the single-dose container and the bottom of the carton after EXP.

Store below 30°C. Protect from light and moisture. Do not freeze. Once the pouch is opened, keep the single-dose ampoules in the pouch and place the pouch back in carton to protect against light and moisture, use within 10 days.

- Disposal

Discard the opened single-dose container immediately after use. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

8. Product Description

- What it looks like

GANFORT® PF is supplied in single-dose low density polyethylene (LDPE)

containers with a twist-off tab. Each single-dose contains 0.4 mL solution.

The two pack sizes are:

- 5 x 0.4 mL single dose containers (physician samples). Five single-dose containers are connected in a strip and packaged in an aluminium pouch.
- 30 x 0.4mL single dose containers. Each five single-dose containers are connected in a strip and two strips are packaged in an aluminium pouch. Three pouches are then placed in an outer carton.

Not all pack sizes may be marketed.

- Ingredients

- Active ingredients
bimatoprost and
timolol

- Inactive ingredients
Sodium chloride, sodium phosphate dibasic heptahydrate, citric acid monohydrate; and purified water. Hydrochloric acid and/or sodium hydroxide may be added to adjust pH.

- MAL number:
MAL18121003ARZ

9. Manufacturer

Allergan Pharmaceuticals Ireland
Castlebar Road Westport
County Mayo Ireland

Product Registration Holder

ABBVIE SDN BHD
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10. Date of revision

05/03/2024

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