

GANFORT® EYE DROPS

Consumer Medication Information Leaflet (RiMUP)

Bimatoprost/timolol (0.3mg/5.0mg per ml)

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What GANFORT® is used for

GANFORT® is prescribed to lower the pressure in the eye of people with glaucoma or high pressure in the eye when other medicines like beta blockers or prostaglandin analogues used alone are not enough.

How GANFORT® works

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

Before you use GANFORT®

- When you must not use it

Do not use GANFORT®:

- if you are allergic (hypersensitive to bimatoprost or timolol, or any of the other ingredients of GANFORT®. (for a full list of ingredients, see section "PRODUCT DESCRIPTION").
- if you have now or have had in the past respiratory problems such as asthma, severe chronic obstructive lung disease.
- 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® if you are pregnant unless your doctor still recommends it.

Do not use GANFORT® 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 and adolescents

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

- Before you start to use it

Take special care with GANFORT®.

Always use GANFORT® 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:

- heart disease or poor blood flow to the heart
- poor blood circulation disease (such as Raynaud's disease or Raynaud's syndrome)
- over activity 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 or kidney problems
- eye surface problems
- eye infection
- 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, eye inflammation or surgery

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

GANFORT® 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 reversible. The change may be more noticeable if you are only treating one eye.

- Taking other medicines

GANFORT® 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 (e.g. beta blockers, prostaglandin analogues, adrenaline, amiodarone)

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.

How to use GANFORT®

- How much to use

Recommended dosage in adults (including the elderly)

The recommended dose is one drop of GANFORT® 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.

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.

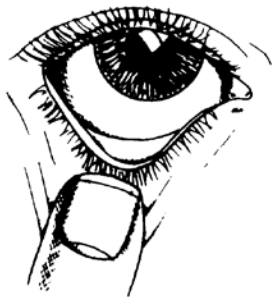
- Instructions for use

You must not use the bottle if the tamper-proof seal on the bottle neck is broken before you first use it.

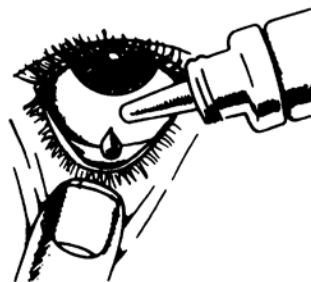
1. Wash your hands. Tilt your head back and look at the ceiling.



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.



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 1 minute. This helps to stop **GANFORT™** getting into the rest of the body.



If a drop misses your eye, try again.

Put the cap back on and close the bottle straight after you have used it.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking **GANFORT®** 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 **GANFORT®** is ingested orally, Timolol overdose may cause symptoms such as slow heartbeat, low blood pressure, shortness of breath,

headache, dizziness, and heart suddenly stops pumping blood.

If you use more **GANFORT®** 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.

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®**.

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® may cause blurred vision in some people. Do not drive or use machines until the symptoms have cleared.

Using contact lenses

GANFORT® contains benzalkonium chloride as a preservative, which is known to discolour soft contact lenses and can cause eye irritation. If you wear soft contact lenses you must remove them before using **GANFORT®** eye drops and wait at least 15 minutes before putting your lenses back in.

Use in kidney and liver impairment

GANFORT® has not been studied in people with liver or kidney impairment. Therefore, caution should be used in treating such people.

Side effects

Like all medicines, **GANFORT®** can cause side effects, although not everybody gets them.

The chance of having a side effect is described by the following categories:

- **Very common:** Occurs in more than 1 out of 10 people
- **Common:** Occurs in fewer than 1 out of 10 people

Affecting the eyes

Very common: Redness of the eye, growth of eyelashes

Common:

- Inflammation of the surface of the eye
- Superficial damage to the front part of the eye
- Burning or itchy or stinging eyes, a feeling that something is in your eye
- Dry eyes
- Eye pain
- Light sensitivity
- Sticky eyes
- Visual disturbance
- Itchy eyelids
- Darkening of the eyelids

Additional side effects have been seen with brimonidine or timolol and therefore may potentially occur with **GANFORT®**.

Bimatoprost

- Dizziness
- Eye allergy
- Eyelash darkening
- Increased darkening or browning of the colored part of the eye
- Eyelid twitching
- Eyelid shrinking
- Bleeding of the retina
- Inflammation inside the eye
- High blood pressure
- Feeling weak
- Abnormal liver function tests (LFT)

Timolol:

- Itchy skin rash
- Low blood sugar level

- Nervousness, hear, smell, taste or feel things that do not exist, disorientation, confusion, anxiety, difficulty in sleeping, depression, nightmares, memory loss, feeling drowsy or sleepy
- Increase in signs and symptoms muscle weakness and fatigue, prickling skin, lack of oxygen to the brain
- Eye-surface scarring, decreased eye sensitivity, double vision, droopy eyelid, choroid layer detachment (following eye surgery), blurred vision, eye power changes.
- Abnormal heart rhythm, congestive heart failure, death associated with heart failure, irregular heartbeat, feeling faint, slow heartbeat, low blood pressure, chest pain, water retention
- Cold or numb hands and feet
- Difficulty breathing, death associated with difficulty breathing, shortness of breath, water retention in the lungs, blocked nose, cough
- Loss of appetite, nausea, vomiting, change in sense of taste, abdominal pain, indigestion, diarrhoea, dry mouth
- Hair loss
- Formation of scar tissue in the penis.
- Decreased sex drive

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 calling Tel: 03-78835549, or visiting the website npra.moh.gov.my (Public → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI))

Storage and Disposal of GANFORT®

- Storage

On prescription only. Keep out of reach of children. Keep the bottle in the outer carton.

Do not use **GANFORT®** after the expiry date which is stated on the bottle label and the bottom of the carton after EXP.

Store below 25°C.

- Disposal

Dispose 28 days after the bottle has been opened, even if some solution is left.

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.

Product Description

- What it looks like

GANFORT® sterile, clear, colourless to slightly yellow eye drops are supplied in white opaque plastic dropper bottles of 3 mL.

- Ingredients

- Active ingredients
bimatoprost and timolol
- Inactive ingredients
benzalkonium chloride, sodium chloride, dibasic sodium phosphate heptahydrate, citric acid monohydrate, hydrochloric acid or sodium hydroxide (to adjust pH), purified water

- MAL number

MAL20081836AZ

Manufacturer

Allergan Pharmaceuticals Ireland
Castlebar Road
Westport
County Mayo
Ireland

Product Registration Holder

Allergan Malaysia Sdn Bhd
Level 5-02, Block A, PJ8, No.23, Jalan Barat, Seksyen 8, 46050 Petaling Jaya, Selangor, Malaysia

Date of revision

19/06/2018

Serial number

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