
PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

Schedule 4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

GANFORT, bimatoprost and timolol

Bimatoprost 0,3 mg/ml and timolol 5,0 mg/ml eye drops

Read all of this leaflet carefully before you start using GANFORT

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- GANFORT 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.

1. WHAT GANFORT CONTAINS

- The active substances are bimatoprost and timolol maleate. Each ml of GANFORT contains 0,3 mg bimatoprost and 6,8 mg timolol maleate equivalent to 5,0 mg timolol.
- The other ingredients are: benzalkonium chloride 0,005 % m/v (a preservative), citric acid monohydrate, purified water, sodium chloride and sodium phosphate dibasic heptahydrate.

2. WHAT GANFORT IS USED FOR

GANFORT 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). 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.

GANFORT 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 may prescribe GANFORT for you when other eye drops containing only beta-blockers or prostaglandin analogues have not worked sufficiently well.

3. BEFORE YOU USE GANFORT

Do not use GANFORT:

- If you are hypersensitive (allergic) to bimatoprost, timolol, beta-blockers or to any of the other ingredients of GANFORT;

- 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.

Take special care with GANFORT

Before you use GANFORT, 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;
- 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;
- Inflammation inside the eye, e.g. uveitis;
- 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 GANFORT, as timolol may change effects of some medicines used during anaesthesia.

GANFORT 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.

You should not use GANFORT if you are below 18 years of age.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or other healthcare provider for advice before using GANFORT.

GANFORT should not be used during pregnancy.

Do not use GANFORT 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 machinery

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

Important information about some of the ingredients of GANFORT

GANFORT contains a preservative called benzalkonium chloride. Benzalkonium chloride may cause eye irritation and is also known to discolour soft contact lenses. Do not use GANFORT while your contact lenses are in your eyes. Wait at least 15 minutes after using GANFORT before putting your lenses back into your eyes.

Using other medicines with GANFORT

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

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

- Medicines that 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.

4. HOW TO USE GANFORT

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

Always use GANFORT exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dose of GANFORT is one drop once a day, either in the morning or in the evening, in each eye that needs treatment.

Use GANFORT at the same time each day.

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 2 minutes. This helps to stop GANFORT getting into the rest of the body.

If a drop misses your eye, try again.

To avoid contamination (dirtying) the solution, 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 use GANFORT with other eye medicine, leave at least 5 minutes between putting in GANFORT and the other medicine. Use any eye ointment or gel last.

Your doctor will tell you how long your treatment with GANFORT will last. Do not stop treatment early because GANFORT should be used every day to work properly.

If you have the impression that the effect of GANFORT is too strong or too weak for you, tell your doctor or pharmacist.

If you use more GANFORT than you should

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.

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 use GANFORT

Do not use a double dose to make up for a forgotten individual dose. If you forget to use GANFORT, use a single drop as soon as you remember, and then go back to your regular routine.

If you have trouble remembering when to use your medicine, ask your pharmacist for some hints.

Effects when treatment with GANFORT is stopped

GANFORT should be used every day to work properly.

5. POSSIBLE SIDE EFFECTS

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

Do not stop using GANFORT without speaking to your doctor.

The following side effects may be seen with GANFORT:

Frequent: Eye redness, longer eyelashes, burning, itching, stinging, 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, darker skin colour around the eyes

Less frequent: 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, headache, runny nose, hair growing around the eye, darker iris colour, eyes appearing sunken

Not known: Cystoid macular oedema (swelling of the retina within the eye leading to worsening of vision), eye swelling, blurred vision, eye discomfort, slow heart rate, tiredness, allergies including skin allergy and eye allergy, dizziness, changes in your taste sensation, difficulty sleeping, nightmares, asthma, shortness of breath, hair loss, discolouring of skin around the eyes, high blood pressure

Additional side effects have been seen in patients using eye drops containing bimatoprost, as in GANFORT and may also be seen: Infection (primarily colds and upper respiratory symptoms), allergic reaction in the eye, darkening of the eyelashes, increased blinking, bleeding in the back of the eye (retinal bleeding), inflammation within the eye, abnormal hair growth, nausea, weakness, swelling of your hands, feet and extremities, an increase in blood test results that show how your liver is working.

Additional side effects have been seen in patients using eye drops containing timolol as in GANFORT and may also be seen. Timolol is absorbed into the blood. This may cause similar side effects as seen with intravenous and/or oral medicines containing beta-blockers. The chance of having side effects after using eye drops is lower than when medicines are, taken by mouth or injected.

This list of side effects includes reactions seen with most of beta-blockers 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 reactions (including rash, itching, hives);
- Low blood sugar;
- Behavioural changes and psychic disturbances including anxiety, confusion, depression, disorientation, hallucinations, nervousness, drowsiness and 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;
- Refractive changes (due to withdrawal of miotic therapy in some cases);
- Keratitis (inflammation of the front part of the eye); pseudopemphigoid; signs and symptoms of eye irritation including conjunctivitis (inflammation of the see-through layer of the eye);
- Tinnitus;
- Heart failure; Irregularity or stopping of the heartbeat; slow or fast heartbeat; excess fluid in the lungs;
- Too much fluid, mainly water, accumulating in the body;
- Chest pain;
- 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; tightening of the muscles of the lungs;
- Diarrhoea; stomach pain; feeling and being sick;
- Indigestion; dry mouth;
- Red scaly patches on skin; skin rash;
- Muscle pain; systemic lupus erythematosus;
- Reduced sexual urge; sexual dysfunction;
- Peyronie's disease; retroperitoneal fibrosis (abnormal growth of tissue on and around abdominal structures).

If you notice any side effect not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF GANFORT

- Store at or below 25 °C.
- Store all medicines out of the reach of children.

- Do not use GANFORT after the expiry date which is stated on the bottle label and carton after EXP. The expiry date refers to the last day of the month.
- Once opened, solutions may become contaminated, which can cause eye infections. Therefore, you must throw away the bottle 4 weeks after 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. Keep bottle tightly closed when you are not using it.
- Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

7. PRESENTATION OF GANFORT

Each bottle is about half full and contains 3 ml of eye drop solution. This is enough for 4 weeks' usage.

8. IDENTIFICATION OF GANFORT

Clear, colourless to slightly yellow eye drop solution, practically free from particles.

9. REGISTRATION NUMBER

42/15.4/0127

10. NAME AND ADDRESS OF THE REGISTRATION HOLDER

Allergan Pharmaceuticals (Pty) Ltd
30 New Road (entrance off Bavaria Road)
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11. DATE OF PUBLICATION

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Professional Information can be accessed via <http://www.allergan.co.za/en-za/products>
In case of an adverse event please contact +27 11 545 6600 or send an e-mail to
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