

---

## PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS

Schedule 4

### PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

#### **GANFORT, bimatoprost and timolol**

Bimatoprost 0,3 mg 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

Active ingredients: Bimatoprost and timolol maleate

Inactive ingredients: Benzalkonium chloride (a preservative), sodium chloride, sodium phosphate dibasic heptahydrate, citric acid monohydrate and purified water. Small amounts of hydrochloric acid or sodium hydroxide may be added to bring the solution to the correct pH level.

GANFORT has an osmolality of 270 – 310 mOsm/kg.

### 2. WHAT GANFORT IS USED FOR

GANFORT is an eye drop that is used to control glaucoma. It contains two different active substances (bimatoprost and timolol) that both reduce high pressure in the eye. Bimatoprost belongs to a group of medicines called prostamides. Timolol belongs to a group of medicines called beta-blockers. GANFORT is prescribed to reduce high pressure in the eye.

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 it. If the liquid cannot drain out quickly enough, the pressure inside the eye builds up and could eventually damage your sight. 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.

### 3. BEFORE YOU USE GANFORT

#### **Do not use GANFORT:**

- If you are hypersensitive (allergic) to bimatoprost, timolol or any of the other ingredients of GANFORT.
- If you have now or have had in the past any breathing illnesses such as asthma, severe

chronic obstructive lung disease (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 levels (hypoglycaemia);
- 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 of vision, for example, cataract surgery.
- Tell your doctor before surgical anaesthesia that you are using GANFORT, as timolol may change the effects of some of the 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.

GANFORT should not be used if you are below 18 years of age.

**Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, please consult your doctor, pharmacist or other health care provider for advice before using GANFORT.

GANFORT should not be used during pregnancy.

Do not use GANFORT if you are breast-feeding your baby. Timolol may get into your breast milk.

---

### **Driving and using machinery**

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

### **Important information about some of the ingredients of GANFORT**

Do not use the drops while your contact lenses are in your eyes. Wait at least 15 minutes after using the eye drops before putting your lenses back in your eyes. A preservative in GANFORT (benzalkonium chloride) may cause eye irritation and is also known to discolour soft contact lenses.

### **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.

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

## **4. HOW TO USE GANFORT**

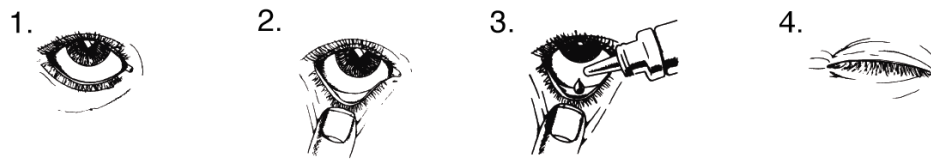
Do not share medicines prescribed for you with any other person.

Always use GANFORT exactly as your doctor has instructed you. You should check with your doctor if you are unsure. If you have the impression that the effect of GANFORT is too strong or too weak, talk to your doctor or pharmacist.

The usual dose is one drop in the morning in each eye that needs treatment. However, your doctor may recommend you apply the drop in the evening instead.

### **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 for 30 seconds.
5. If a drop misses your eye, try again.

To avoid contamination, 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 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 over-dosage, 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 the forgotten individual doses. 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 health care provider for advice.

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

*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

*Not known:* Cystoid macular oedema (swelling of the retina within the eye leading to worsening of vision) , eye swelling, darkening of the iris colour, eyes appearing sunken, 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, darkening/discolouring of skin around the eyes, high blood pressure

The following side effects have been seen with the active ingredients of GANFORT (bimatoprost and timolol) and so may possibly be seen with GANFORT:

Severe allergic reactions with swelling and difficulty breathing which could be life-threatening, allergic reactions (including rash, itching, hives), allergic reaction in the eye, cataract, darkening of the eyelashes, increased blinking, bleeding in the back of the eye (retinal bleeding), inflammation within the eye, abnormal hair growth, nausea, weakness, an increase in blood test results that show how your liver is working, infection (primarily colds and upper respiratory symptoms), low blood sugar, effects on the heart beat including irregularity or stopping of the heart beat, slow or fast heartbeat, chest pain, heart failure, too much fluid (mainly water) accumulating in the body, excess fluid in the lungs, tightening of the muscles of the lungs, 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), red scaly patches on skin, skin rash, difficulty breathing, wheezing, cough, dry mouth, reduced sexual urge, sexual dysfunction, Peyronie's disease, retroperitoneal fibrosis (abnormal growth of tissue on and around abdominal structures), behavioural changes and psychic disturbances including anxiety, confusion, depression, disorientation, hallucinations, nervousness, drowsiness, memory loss, stroke, decreased blood flow to the brain, ringing in the ears and a 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, refractive changes (due to withdrawal of miotic therapy in some cases), keratitis (inflammation of the front part of the eye), pseudophakia, signs and symptoms of eye irritation including conjunctivitis (inflammation of the see-through layer of the eye), diarrhoea, stomach pain, feeling and being sick, indigestion, muscle pain, systemic lupus erythematosus

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

---

## **6. STORING AND DISPOSING OF GANFORT**

Store below 25 °C. KEEP ALL MEDICINES OUT OF REACH OF CHILDREN. Do not use the eye drops after the expiry date printed on the carton and bottle. 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 contains 3 ml of eye drop solution.

## **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 BUSINESS ADDRESS OF REGISTRATION HOLDER**

Allergan Pharmaceuticals (Pty) Ltd  
30 New Road (entrance off Bavaria Road)  
Randjespark Ext. 11, Midrand, 1682  
Johannesburg, Gauteng,  
SOUTH AFRICA

Telephone number: +27 (0) 11 545 6600

## **11. DATE OF PUBLICATION**

Date of registration: 09 October 2009

Date of revision of the most recently revised Patient Information Leaflet as approved by the Authority: 09 October 2009

Professional Information can be accessed via <http://www.allergan.co.za/en-za/products>

In case of an adverse event / side effect, please contact +27 (0) 11 545 6600 or send an email to SA\_Complaints@Allergan.com