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## PATIENT INFORMATION LEAFLET

**Please read this leaflet carefully before using GANFORT Eye Drops.**

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

**Scheduling Status:** Schedule 4

**Proprietary name, Strength and Pharmaceutical Form:**  
**GANFORT Eye Drops**

Each ml contains bimatoprost 0,3 mg and timolol maleate equivalent to 5,0 mg timolol.

### 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.

### 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.

### BEFORE YOU TAKE GANFORT

**Do not take GANFORT:**

- If you are hypersensitive (allergic) to bimatoprost, timolol or any of the other ingredients of GANFORT.
- If you have any breathing illnesses such as asthma or a history of asthma, or severe chronic obstructive lung disease.
- If you have heart problems such as heart weakness or heart beat disorders.

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**Take special care with GANFORT:**

Before you use this medicine, tell your doctor:

If you have now or have had in the past any of the following: heart, blood pressure or breathing problems, overactivity of the thyroid, diabetes or low blood sugar levels (hypoglycaemia), severe allergic reactions, liver or kidney problems.

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 in people under 18 unless your doctor still recommends it.

**Pregnancy and breast-feeding**

If you are pregnant or breast-feeding your baby while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice. Tell your doctor if you are pregnant or planning to become pregnant. GANFORT should not be used during pregnancy.

GANFORT should not be used if you are breast-feeding.

**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**

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of GANFORT with these medicines may cause undesirable interactions. Tell your doctor or pharmacist if you are taking any other medicines, including any you have bought at your pharmacy, supermarket or health food shop. Please consult your doctor, pharmacist or other healthcare professional for advice.

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.

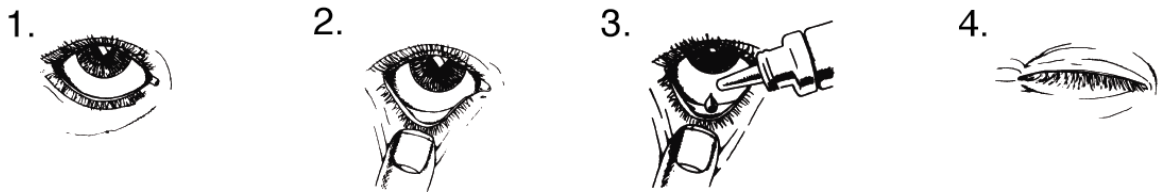
## HOW TO USE GANFORT

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.
- 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.

### 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.

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## POSSIBLE SIDE EFFECTS

GANFORT can have side effects. Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

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

*Very common:* Occurs in more than 1 out of 10 patients

*Common:* Occurs in between 1 and 10 out of every 100 patients

*Uncommon:* Occurs in between 1 and 10 out of every 1 000 patients

The following eye side effects may be seen with GANFORT:

*Very common:* Eye redness, longer eyelashes

*Common:* 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

*Uncommon:* Watery eyes, swollen or painful eyelids, tired eyes, in-growing eyelashes, headache, runny nose, hair growing around the eye

The following side effects have been seen with the active ingredients of GANFORT (bimatoprost and timolol) and so may possibly be seen with GANFORT. Allergic reaction in the eye, cataract, darkening of the eyelashes, darkening of the iris colour, dizziness, high blood pressure, an increase in blood test results that show how your liver is working, cold, effects on the heart beat, heart failure, increased heart rate, low blood pressure, skin rash, cough, dry mouth, hair loss, nightmares, reduced sexual urge, memory loss, tiredness, ringing in the ears and a worsening of myasthenia gravis (increased muscle weakness).

If any of the side effects get serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

## 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).

### **PRESENTATION OF GANFORT**

Each bottle contains 3 ml of eye drop solution.

### **IDENTIFICATION OF GANFORT**

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

### **REGISTRATION NUMBER**

42/15.4/0127

### **NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION**

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### **DATE OF PUBLICATION OF THIS PATIENT INFORMATION LEAFLET**

9 October 2009