

PACKAGE LEAFLET: INFORMATION FOR THE USER

GANFORT®

300 micrograms/ml + 5 mg/ml eye drops, solution
bimatoprost and timolol maleate

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What GANFORT is and what it is used for
2. Before you use GANFORT
3. How to use GANFORT
4. Possible side effects
5. How to store GANFORT
6. Further information

1. WHAT GANFORT IS AND WHAT IT 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 this. 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.

2. BEFORE YOU USE GANFORT

Do not use GANFORT:

- If you are allergic (hypersensitive) 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

Take special care with GANFORT:

Before you use this medicine, tell your doctor

- if you have now or have had in the past
 - 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 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.

GANFORT should not be used in people under 18 unless your doctor still recommends it.

Using other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

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.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine. Tell your doctor if you are pregnant or planning to become pregnant. GANFORT should not be used during pregnancy unless your doctor still recommends it.

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

Driving and using machines

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.

3. HOW TO USE GANFORT

Always use GANFORT exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. 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

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

If you stop using GANFORT

GANFORT should be used every day to work properly.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE 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 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 bimatoprost or 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 effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE GANFORT

Keep out of the reach and sight of children.

Do not use GANFORT after the expiry date which is stated on the bottle label and the carton after EXP:. The expiry date refers to the last day of that month.

Store below 25°C.

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.

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.

6. FURTHER INFORMATION

What GANFORT contains

- The active substances are bimatoprost 0.3 mg/ml and timolol 5 mg/ml corresponding to timolol maleate 6.8 mg/ml.
- The other ingredients are 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.

What GANFORT looks like and contents of the pack

GANFORT is a colourless, clear eye drop solution in a plastic bottle. Each pack contains either 1 or 3 plastic bottles each with a screw-cap. Each bottle is about half full and contains 3 millilitres of solution. This is enough for 4 weeks' usage. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

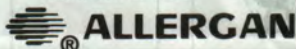
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This leaflet was last approved in May 2006.

(THIS IS A MEDICAMENT)

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep medicament out of reach of children

Council of Arab Health Ministers
Union of Arab Pharmacists



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