

Package leaflet: Information for the user

GANFORT 0.3 mg/ml + 5 mg/ml eye drops, solution, in single-dose container Bimatoprost/timolol

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What GANFORT single-dose is and what it is used for
2. What you need to know before you use GANFORT single-dose
3. How to use GANFORT single-dose
4. Possible side effects
5. How to store GANFORT single-dose
6. Contents of the pack and other information

1. What GANFORT single-dose is and what it is used for

GANFORT single-dose 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 single-dose 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 single-dose 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 will prescribe you GANFORT single-dose when other eye drops containing beta-blockers or prostaglandin analogues have not worked sufficiently on their own.

This medicine does not contain a preservative.

2. What you need to know before you use GANFORT single-dose

Do not use GANFORT single-dose eye drops, solution

- if you are allergic to bimatoprost, timolol, beta-blockers or any of the other ingredients of GANFORT single-dose (listed in section 6)
- if you have now or have had in past respiratory problems such as asthma and/or severe chronic obstructive pulmonary disease (lung disease which may cause wheeziness, difficulty in breathing and/ or long-standing cough) or other types of breathing problems
- if you have heart problems such as low heart rate, heart block, or heart failure

Warnings and precautions

Before you use this medicine, 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 reaction
- liver or kidney problems
- eye surface problems
- 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 single-dose as timolol may change effects of some medicines used during anaesthesia.

GANFORT single-dose may cause your eyelashes to darken and grow, and cause the skin around the eye 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 single-dose may cause hair growth when in contact with the skin surface.

Children and adolescents

GANFORT single-dose should not be used in children and teenagers under 18.

Other medicines and GANFORT single-dose

GANFORT single-dose can affect or be affected by other medicines you are using, including other eye drops for the treatment of glaucoma. Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Tell your doctor if you are using or intend to use medicines to lower blood pressure, heart medicine, medicines to treat diabetes, quinidine (used to treat heart conditions and some types of malaria) or medicines to treat depression known as fluoxetine and paroxetine.

Pregnancy and breast-feeding

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 single-dose if you are pregnant unless your doctor still recommends it.

Do not use GANFORT single-dose if you are breast-feeding. Timolol may get into your breast milk. Ask your doctor for advice before taking any medicine during breast-feeding.

Driving and using machines

GANFORT single-dose may cause blurred vision in some patients. Do not drive or use machines until the symptoms have cleared.

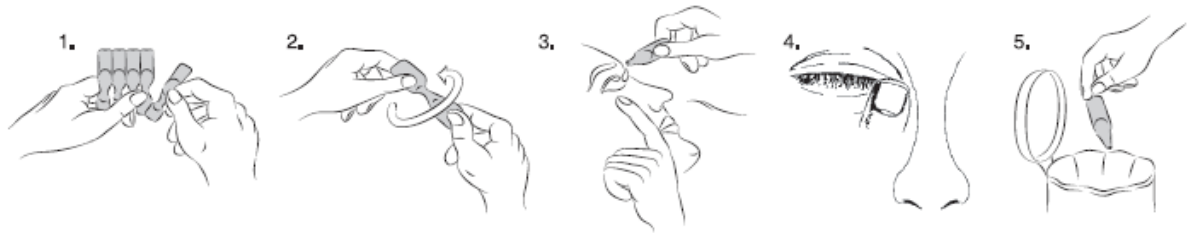
3. How to use GANFORT single-dose

Always use GANFORT single-dose exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is one drop once a day, either in the morning or in the evening in each eye that needs treatment. Use at the same time each day.

Instructions for use

Wash your hands before use. Make sure that the single-dose container is intact before use. The solution should be used immediately after opening. To avoid contamination, do not let the open-end of the single-dose container touch your eye or anything else.



1. Tear 1 single-dose container from the strip.
2. Hold the single-dose container upright (with the cap pointing upwards) and twist off the cap.
3. Gently pull down the lower eyelid to form a pocket. Turn the single-dose container upside down and squeeze it to release 1 drop into the affected eye(s).
4. 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 single-dose getting into the rest of the body.
5. Throw away the single-dose container after you have used it, even if there is some solution left.

If a drop misses your eye, try again. Wipe off any excess that runs down the cheek.

If you wear contact lenses, take your lenses out before using this medicine. Wait 15 minutes after using the drops, and before you put your lenses back in.

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

If you use more GANFORT single-dose than you should

If you use more GANFORT single-dose 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 single-dose

If you forget to use GANFORT single-dose, 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 single-dose

GANFORT single-dose should be used every day to work properly.

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

4. Possible side effects

Like all medicines, GANFORT single-dose can cause side effects, although not everybody gets them. You can usually carry on taking the drops, unless the effects are serious. If you're worried, talk to a doctor or pharmacist. Do not stop using GANFORT single-dose without speaking to your doctor.

The following side effects may be seen with GANFORT (single-dose and/or multi-dose):

Very common side effects

These may affect more than 1 user in 10

Affecting the eye

redness.

Common side effects

These may affect 1 to 9 users in 100

Affecting the eye

burning, itching, stinging, irritation of the conjunctiva (see-through layer of the eye), 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, hair growing around the eye, darkening of the eyelids, darker skin colour around the eyes, longer eyelashes, eye irritation, watery eyes, swollen eyelids, reduced vision.

Affecting other parts of the body

runny nose, headache.

Uncommon side effects

These may affect 1 to 9 users in 1,000

Affecting the eye

abnormal sensation in the eye, iris inflammation, swollen conjunctiva (see-through layer of the eye), painful eyelids, tired eyes, in-growing eyelashes, darkening of iris colour, eyes appear sunken, eyelid drooping, eyelid shrinking (moving away from the surface of the eye leading to incomplete closure of the eyelids), skin tightness of the eyelids, darkening of eyelashes.

Affecting other parts of the body

shortness of breath.

Side effects where the frequency is not known

Affecting the eye

cystoid macular oedema (swelling of the retina within the eye leading to worsening vision), eye swelling, blurred vision, ocular discomfort.

Affecting other parts of the body

difficulty breathing / wheezing, symptoms of allergic reaction (swelling, redness of the eye and rash of the skin), changes in your taste sensation, dizziness, slowing of heart rate, high blood pressure, difficulty sleeping, nightmare, asthma, hair loss, skin discolouration (periocular), tiredness.

Additional side effects have been seen in patients using eye drops containing timolol or bimatoprost and so may possibly be seen with GANFORT. Like other medicines applied into eyes, timolol is absorbed into the blood. This may cause similar side effects as seen with "intravenous" and/or "oral" beta-blocking agents. The chance of having side effects after using eye drops is lower than when medicines are for example, taken by mouth or injected. Listed side effects include reactions seen within bimatoprost and timolol when used for treating eye conditions:

- Severe allergic reactions with swelling and difficulty breathing which could be life-threatening
- Low blood sugar
- Depression; memory loss; hallucination
- 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, bleeding in the back of the eye (retinal bleeding), inflammation within the eye, increased blinking

- Heart failure; irregularity or stopping of the heartbeat; slow or fast heartbeat; too much fluid, mainly water, accumulating in the body; chest pain
- Low blood pressure, swelling or coldness of your hands, feet and extremities, caused by constriction of your blood vessels
- Cough, worsening of asthma, worsening of the lung disease called chronic obstructive pulmonary disease (COPD)
- Diarrhoea; stomach pain; feeling and being sick; indigestion; dry mouth
- Red scaly patches on skin; skin rash
- Muscle pain
- Reduced sexual urge; sexual dysfunction
- Weakness
- An increase in blood test results that show how your liver is working

Other side effects reported with eye drops containing phosphates

This medicine contains 0.38 mg phosphates in each 0.4 ml of solution which is equivalent to 0.95 mg/ml. If you suffer from severe damage to the clear layer at the front of the eye (the cornea), phosphates may cause in very rare cases cloudy patches on the cornea due to calcium build-up during treatment.

Reporting side effects

If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

UK

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store GANFORT single-dose

Keep GANFORT single-dose out of the sight and reach of children.

Do not use GANFORT single-dose after the expiry date which is stated on the single-dose container and the carton. The expiry date refers to the last day of that month.

This medicine is for single use only and does not contain preservatives. Do not keep any unused solution.

This medicinal product does not require any special temperature storage conditions. Keep the single-dose containers in the pouch and place the pouch back in carton in order to protect from light and moisture. Once the single-dose container is removed from the pouch use within 7 days. All single-dose containers should be kept in the pouch and discarded after 10 days from the first opening of the pouch.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What GANFORT single-dose 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 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 (acidity) level.

What GANFORT single-dose looks like and contents of the pack

GANFORT single-dose is a colourless to slightly yellow solution supplied in single-dose plastic containers, each containing 0.4 ml of solution.

Pack contains 1 foil pouch containing 5 single-dose containers in a carton.

Packs contain 3 or 9 foil pouches, each containing 10 single-dose containers, for a total of 30 or 90 single-dose containers in a carton, respectively.

Not all pack sizes may be marketed.

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