

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations)
- 1986

This medicine is dispensed with a doctor's prescription only

Ganfort[®]
Eye drops

Active ingredients and its concentration:

bimatoprost 0.03% w/v and timolol (as maleate) 0.5% w/v

Inactive ingredients and allergens in this medicine: See section 2 under "Important information about some of this medicine's ingredients" and section 6 "Additional information".

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed to treat your illness/for you. Do not pass it on to others. It may harm them, even if it seems to you that their illness/medical condition is similar to yours.

1. What is this medicine intended for?

Ganfort is used to reduce pressure in the eyes of patients who have open-angle glaucoma or high pressure in the eye and whose response to local treatment with beta-blockers or prostaglandin analogues has been insufficient.

Therapeutic group: timolol - beta-blockers, bimatoprost - prostamides, prostaglandin analogues.

This medicine contains two different active ingredients 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. The 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 vision (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.

2. Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredients bimatoprost, timolol, to beta-blockers or any of the other ingredients in this medicine (listed in section 6 "Additional information").
- You suffer now or had suffered in the past from breathing 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.
- You suffer from heart problems such as low heart rate, heart block, or heart failure.

Special warnings about using this medicine

Before treatment with 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
- heart rate disturbances such as slow heartbeat
- breathing problems, asthma or chronic obstructive pulmonary disease
- poor blood circulation disease (such as Raynaud's disease or Raynaud's syndrome)
- over-activity of the thyroid gland, because timolol may mask signs and symptoms of thyroid disease
- diabetes, because timolol may mask signs and symptoms of low blood sugar level
- severe allergic reactions
- 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 edema (swelling of the retina within the eye leading to worsening vision), for example, cataract surgery

Tell your doctor before surgical anesthesia that you are using Ganfort because timolol may change the effects of certain medicines used during anesthesia.

Ganfort may cause your eyelashes to darken and grow and cause the skin around the eyelid to darken too. The color 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 may cause hair growth when in contact with the skin.

Children and adolescents

Do not use Ganfort in children and adolescents under 18.

Interactions/Drug interactions

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist. Ganfort can affect or be affected by other medicines you are using, including other eye drops for the treatment of glaucoma.

Particularly, tell your doctor or pharmacist 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 certain types of malaria) or medicines to treat depression such as fluoxetine and paroxetine.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, 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 if you are pregnant unless your doctor still recommends it. Do not use Ganfort if you are breastfeeding. Timolol can pass into your breast milk. Ask your doctor for advice before taking any medicine during breastfeeding. There is no information about the effect of Ganfort on fertility.

Driving and using machines

Ganfort may cause blurred vision in some patients. Do not drive or operate machines until the symptoms have cleared.

Important information about some of this medicine's ingredients

Ganfort contains a preservative called benzalkonium chloride.

This medicine contains 0.15 mg of benzalkonium chloride in each 3 ml of solution, which is equivalent to 0.05 mg/ml.

Benzalkonium chloride may be absorbed by soft contact lenses and may change their color. You should remove your contact lenses before using this medicine. You may put them back on only after you have waited 15 minutes after using this medicine.

Benzalkonium chloride may also cause eye irritation, particularly if you have dry eyes or disorders of the cornea (the clear layer at the front of your eye). If you feel any abnormal sensation, stinging or pain in your eye after using this medicine, consult with your doctor.

Ganfort contains 2.85 mg of phosphates in each 3 ml of solution, which is equivalent to 0.95 mg/ml (see also section 4, "Other side effects reported with eye drops containing phosphates").

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about the dosage or the treatment regimen of this medicine.

The dosage and treatment will be determined by the doctor only.

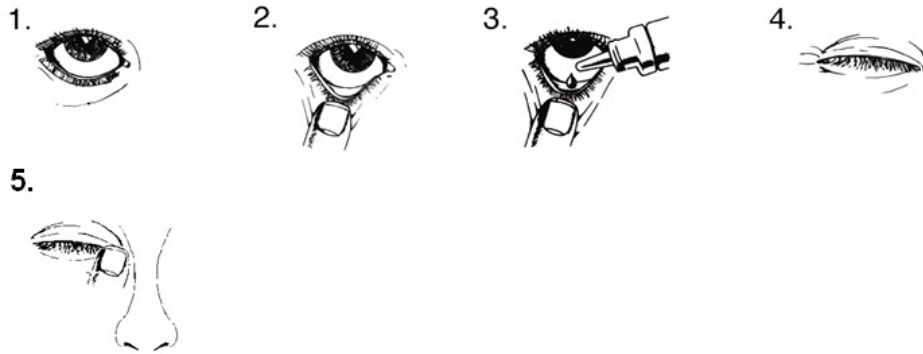
The usual recommended dosage in adults is one drop once a day, either in the morning or in the evening in each eye that needs treatment. Use at the same time each day.

Do not exceed the recommended dose.

Do not swallow.

Instructions for use:

Do 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 eyelid and close your eye.
5. Keeping your eye closed, press your finger against the corner of the closed eye (in the place where the eye meets the nose) and hold for 2 minutes. This helps to stop the medicine from getting into the rest of your body.

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 Ganfort with another eye medicine, wait at least 5 minutes between putting in Ganfort and the other medicine. Use any eye ointment or eye gel last.

If you have accidentally taken too much medicine

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 a child has accidentally swallowed the medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forget to take the medicine

If you forget to take Ganfort, put a single drop in as soon as you remember, and then go back to your regular schedule. Do not put in a double dose to make up for a forgotten dose.

Adhere to the treatment as recommended by your doctor.

Even if your health improves, do not stop taking this medicine without consulting your doctor.

If you stop taking this medicine

Ganfort should be used every day to work properly.

Do not take medicines in the dark! Check the label and dose each time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

As with any medicine, using Ganfort may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Usually, you will be able to continue using the drops, unless the side effects are serious. If you are worried, consult your doctor or pharmacist. Do not stop using Ganfort without consulting your doctor.

The following side effects may be seen with Ganfort:

Very common side effects

Effects that occur in more than one in ten users

Affecting the eye

redness.

Common side effects

Effects that occur in 1-9 in 100 users

Affecting the eye

burning, itching, stinging, irritation of the conjunctiva (transparent layer of the eye), sensitivity to light, eye pain, sticky eyes, dry eyes, a feeling of having a foreign body 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, darkening of the skin color 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

Effects that occur in 1-9 in 1,000 users

Affecting the eye

abnormal sensation in the eye, iris inflammation, swollen conjunctiva (transparent layer of the eye), painful eyelids, tired eyes, in-growing eyelashes, darkening of iris color, 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 of unknown frequency (the frequency of these effects has not been established yet)

Affecting the eye

cystoid macular edema (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, nightmares, asthma, hair loss, skin discolouration (periocular), tiredness.

Additional side effects have been seen in patients using eye drops containing timolol or bimatoprost, so they may possibly be seen with Ganfort use. Like other medicines applied into eyes, timolol is absorbed into the blood. This can cause similar side effects as seen with “intravenous” and /or “oral” beta-blocking medicines. The chance of having side effects after using eye drops is lower than when medicines are, for example, taken by mouth or injected. The side effects listed below include reactions seen while using timolol and bimatoprost when they were used to treat eye conditions:

- severe allergic reactions with swelling and difficulty breathing which could be life-threatening
- low blood sugar level
- 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)
- diarrhea; 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 for liver function

Other side effects reported with eye drops containing phosphates

This medicine contains 2.85 mg phosphates in each 3 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 your eye (the cornea), phosphates may cause, in very rare cases, cloudy patches on the cornea due to calcium build-up during the treatment.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects

You can report side effects to the Ministry of Health by following the link ‘Reporting Side Effects of Drug Treatment’ on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link:

<https://sideeffects.health.gov.il>

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the bottle label and on the carton. The expiry date refers to the last day of that month.
- **Storage conditions:** Store below 25°C.
- Once opened, solutions may become contaminated, which may cause eye infections. Therefore, you must throw away the bottle 28 days after you first opened it, even if some solution is left. To help you remember, write down on the carton the date that you opened it.
- Do not throw away the medicine via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredients, this medicine also contains:

sodium chloride, sodium phosphate dibasic heptahydrate, citric acid monohydrate, benzalkonium chloride, hydrochloric acid or sodium hydroxide for pH adjustment and purified water.

What the medicine looks like and contents of the pack:

Ganfort is a colorless to slightly yellow, clear eye drop solution in a plastic bottle with a screw-cap. The bottle is about half full and contains 3 ml of solution.

Registration holder's name and address: AbbVie Biopharmaceuticals Ltd., 4 Haharash St., Hod Hasharon, Israel.

Manufacturer's name and address: Allergan Pharmaceuticals Ireland, Castlebar Road, Westport, County Mayo, Ireland.

Revised in March 2023 according to MOH guidelines.

Registration number of the medicine in the Ministry of Health's National Drug Registry: 143-64-31608