# PATIENT INFORMATION LEAFLET

**SCHEDULING STATUS:** S4

## GANFORT 0,3 mg/ml + 5,0 mg/ml eye drops, solution
## Bimatoprost and timolol

**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, pharmacist, nurse or other health care provider.
- 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.

**What is in this leaflet**

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

### 1. What GANFORT is and what it is used for

GANFORT 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 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 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 may prescribe GANFORT for you when

other eye drops containing only beta-blockers or prostaglandin analogues have not worked sufficiently well.

## 2. What you need to know before you use GANFORT

### Do not use GANFORT

- If you are hypersensitive (allergic) to bimatoprost, timolol, beta-blockers or to any of the other ingredients of GANFORT (listed in section 6);
- If you have now or have had in the past respiratory problems such as asthma, severe chronic obstructive pulmonary disease (severe 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 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;
- 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 vision), for example, cataract surgery.

Tell your doctor before surgical anaesthesia that you are using GANFORT, as timolol may change effects of some 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 may cause hair growth when in contact with the skin surface.

**Children and adolescents**

GANFORT should not be used in children and teenagers under 18 years of age.

**Other medicines and GANFORT**

GANFORT can affect or be affected by other medicines you are using, including other eye drops for the treatment of glaucoma.

Always tell your health care provider if you are taking any other medicine. (This includes all 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.

**Pregnancy and breastfeeding**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, 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 breastfeeding your baby. Timolol may get into your breast milk. Ask your doctor for advice before taking any medicine if you are breastfeeding.

**Driving and using machines**

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

**GANFORT contains benzalkonium chloride**

GANFORT contains a preservative called benzalkonium chloride.

GANFORT contains 0,15 mg 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 the colour of the contact lenses. Do not use GANFORT while your contact lenses are in your eyes. Wait at least 15 minutes after using GANFORT before putting your lenses back into your eyes.

Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or disorders of the cornea (the clear layer at the front of the eye). If you feel abnormal eye sensation, stinging or pain in the eye after using GANFORT, talk to your doctor.

## 3. How to use GANFORT

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

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

The usual dose of GANFORT is one drop once a day, either in the morning or in the evening, in each eye that needs treatment.

Use GANFORT at the same time each day.

**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.
5. 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 getting into the rest of the body.

If a drop misses your eye, try again.

To avoid contamination (dirtying) the solution, 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 other eye medicine, leave at least 5 minutes between putting in GANFORT and the other medicine. Use any eye ointment or gel last.

Your doctor will tell you how long your treatment with GANFORT will last. Do not stop treatment early because GANFORT should be used every day to work properly. If you have the impression that the effect of GANFORT is too strong or too weak, tell your doctor or pharmacist.

**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 overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

**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 forgotten individual doses. If you have trouble remembering when to use your medicine, ask your pharmacist for some hints.

**If you stop using GANFORT**

GANFORT should be used every day to work properly.

## 4. 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.

Do not stop using GANFORT without speaking to your doctor.

The following side effects may be seen with GANFORT:

***Frequent side effects***

*Affecting the eye*

Eye redness, longer eyelashes, small breaks in the surface of the eye with or without inflammation, burning, irritation of the conjunctiva (see-through layer of the eye), itching, stinging, a feeling of something in the eye, dry eyes, redness and itching of the eyelids, eye pain, sensitivity to light, sticky eyes, difficulty in seeing clearly, reduced vision, inflamed and/or swollen eyelids, eye irritation, increase in tears, darkening of the eyelids, darker skin colour around the eyes

*Affecting other parts of the body*

Headache, runny nose, excessive hair growth

***Less frequent side effects***

*Affecting the eye*

Inflammation of the iris (coloured part of the eye), swollen conjunctiva (see-through layer of the eye), painful eyelids, abnormal feeling in the eye, tired eyes, in-growing eyelashes, darker iris colour, eyes appearing 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, watery eyes

*Affecting the rest 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 of vision), eye swelling, blurred vision, eye discomfort, discolouring of skin around the eyes

*Affecting the rest of the body*
Symptoms of allergic reaction (swelling, redness of the eye and rash of the skin), difficulty sleeping, nightmares, changes in your taste sensation, dizziness, slow heart rate, high blood pressure, tightening of the muscles of the lungs, asthma, hair loss, tiredness

Additional side effects have been seen in patients using eye drops containing bimatoprost, as in GANFORT and may also be seen: Increased blinking, bleeding in the back of the eye (retinal bleeding), inflammation within the eye (uveitis), allergic reaction in the eye, worsening of asthma, worsening of the lung disease called chronic obstructive pulmonary disease (COPD), nausea, abnormal hair growth, weakness, swelling of your hands, feet and extremities, an increase in blood test results that show how your liver is working, infection (primarily colds and upper respiratory symptoms).

Additional side effects have been seen in patients using eye drops containing timolol as in GANFORT and may also be seen. Timolol is absorbed into the blood. This may cause similar side effects as seen with intravenous and/or oral medicines containing beta-blockers. The chance of having side effects after using eye drops is lower than when medicines are, taken by mouth or injected.

This list of side effects includes reactions seen with most of beta-blockers when used for treating eye conditions:

- Severe allergic reactions with swelling and difficulty breathing which could be life-threatening;
- Allergic reactions (including rash, itching, hives);
- Low blood sugar;
- Behavioural changes and psychic disturbances including depression, memory loss, hallucinations, anxiety, disorientation, confusion, nervousness and drowsiness;
- Fainting; stroke;
- Worsening of myasthenia gravis (increased muscle weakness); tingling sensation;
- Decreased blood flow to the brain;
- 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, keratitis (inflammation of the surface of the eye);
- Refractive changes (due to withdrawal of miotic therapy in some cases);

- Pseudopemphigoid, signs and symptoms of eye irritation including conjunctivitis (inflammation of the see-through layer of the eye);
- Tinnitus;
- Heart failure, irregularity or stopping of the heartbeat, slow or fast heartbeat, chest pain;
- Too much fluid, mainly water, accumulating in the body; excess fluid in the lungs;
- Low blood pressure, coldness of your hands, feet and extremities, caused by constriction of your blood vessels; pain or cramping in the lower leg caused by inadequate blood flow to the muscles;
- Cough, blocked nose, difficulty breathing, wheezing, upper respiratory infection;
- Diarrhoea, indigestion, dry mouth, stomach pain, vomiting, loss of appetite;
- Red scaly patches on skin, skin rash;
- Muscle pain, systemic lupus erythematosus;
- Sexual dysfunction, reduced sexual urge, Peyronie's disease, retroperitoneal fibrosis (abnormal growth of tissue on and around abdominal structures).

*Other side effects reported with eye drops containing phosphates*
GANFORT 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 the eye (the cornea), phosphates may cause in very rare cases cloudy patches on the cornea due to calcium build-up during treatment.

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

**Reporting of side effects**
If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reactions Reporting Form"**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8
By reporting side effects, you can help provide more information on the safety of GANFORT.

You can also report side effects to AbbVie (Pty) Ltd by sending an e-mail to MEAPV@abbvie.com

## 5. How to store GANFORT

- Store at or below 25 ºC.
- Store all medicines out of the reach of children.

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

## 6. Contents of the pack and other information

### What GANFORT contains

- The active substances are bimatoprost and timolol maleate. Each ml of GANFORT contains 0,3 mg bimatoprost and 6,8 mg timolol maleate equivalent to 5,0 mg timolol.
- The other ingredients are: benzalkonium chloride 0,005 % m/v (a preservative), citric acid monohydrate, purified water, sodium chloride and sodium phosphate dibasic heptahydrate. 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 clear, colourless to slightly yellow eye drop solution, practically free from particles. Each bottle is about half full and contains 3 ml of eye drop solution. This is enough for 4 weeks' usage.

### Holder of Certificate of Registration

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## Access to corresponding Professional Information

For the professional information, please email medicalinfo.za@abbvie.com

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