PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

GANFORT UD 0,3 mg/ml + 5,0 mg/ml eye drops, solution, in single-dose container

Bimatoprost and timolol

Read all of this leaflet carefully before you start using GANFORT UD

- 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 UD 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.

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

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

GANFORT UD 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 UD 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 UD 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 UD for you when other eye drops containing only 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 UD

Do not use GANFORT UD

- If you are hypersensitive (allergic) to bimatoprost, timolol, beta-blockers or to any of the other ingredients of GANFORT UD (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 UD, 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 UD, as timolol may change effects of some medicines used during anaesthesia.

GANFORT UD 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 UD may cause hair growth when in contact with the skin surface.

Children and adolescents

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

Other medicines and GANFORT UD

GANFORT UD 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 UD.

GANFORT UD should not be used during pregnancy.

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

3. How to use GANFORT UD

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

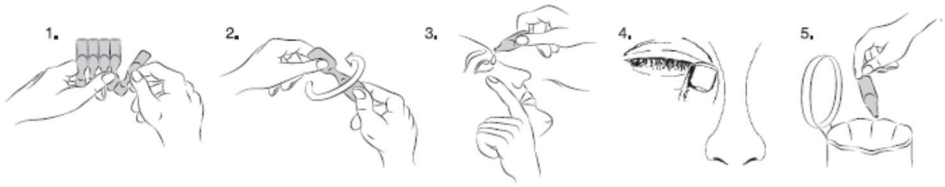
Always use GANFORT UD exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

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

Use GANFORT UD 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.



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 UD 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.

To avoid contamination, do not let the open-end of the single-dose container touch you eye or anything else.

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

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

If you use more GANFORT UD than you should

If you use more GANFORT UD 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 UD

If you forget to use GANFORT UD, 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 UD

GANFORT UD should be used every day to work properly.

4. Possible side effects

GANFORT UD can have side effects. Not all side effects reported for GANFORT UD are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using GANFORT UD, please consult your health care provider for advice.

Do not stop using GANFORT UD without speaking to your doctor.

The following side effects may be seen with GANFORT UD:

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 UD 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 UD 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 UD 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.

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of GANFORT UD.

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

5. How to store GANFORT UD

- Store at or below 25 ºC.
- Store all medicines out of the reach of children.
- Do not use GANFORT UD after the expiry date which is stated on the single-dose container and carton. The expiry date refers to the last day of the month.
- GANFORT UD is for single use only and does not contain preservatives. Do not keep any unused solution.
- GANFORT UD 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.
- 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 UD contains

- The active substances are bimatoprost and timolol maleate. Each ml of GANFORT UD contains 0,3 mg bimatoprost and 6,8 mg timolol maleate equivalent to 5,0 mg timolol.
- 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 UD looks like and contents of the pack

GANFORT UD is a clear, colourless to slightly yellow, isotonic and sterile 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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Access to corresponding Professional Information

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

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