PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

This medicine can be sold under doctor's prescription only

TILOPTIC® 0.5%
Ophthalmic Solution

The ophthalmic solution contains: Timolol (as maleate) 5 mg/ml
For a list of inactive ingredients see section 6.1 "What **TILOPTIC** contains". See also section 2.6 "**Important information about some of the ingredients of TILOPTIC".**

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

- This leaflet contains concise information about **TILOPTIC.** If you have any further questions, 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 medical condition seems similar to yours.
- This medicine is not intended for use in children and infants.

1. WHAT TILOPTIC IS AND WHAT IT IS USED FOR?

Timolol lowers the intraocular pressure. **TILOPTIC** is used to treat glaucoma and to reduce elevated intraocular pressure.
Therapeutic group: beta blockers.

2. BEFORE YOU USE TILOPTIC

2.1 Do not use TILOPTIC if:

- you are hypersensitive (allergic) to timolol, beta-blockers or any of the other ingredients of **TILOPTIC** (for a list of inactive ingredients, see section 6.1).
- you are suffering or have suffered in the past from respiratory problems such as asthma, severe chronic obstructive bronchitis (severe lung disease which may cause wheeziness, difficulty in breathing and/or long-standing cough)
- you have heart problems
- slow heartbeat
- disorders of heart rhythm (irregular heartbeats)
- heart failure
- "cardiogenic shock" – a serious heart condition caused by very low blood pressure, which may result in the following symptoms: dizziness and lightheadedness, fast pulse rate, white skin, sweating, restlessness, loss of consciousness.

If you are not sure whether you should use **TILOPTIC** talk to your doctor or pharmacist**.**

2.2 Special warnings concerning use of TILOPTIC

Before starting treatment with TILOPTIC, tell your doctor if you are suffering or have suffered in the past from:

- 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)
- diabetes as timolol may mask signs and symptoms of low blood sugar
- overactivity of the thyroid gland as timolol may mask signs and symptoms
- if you wear soft contact lenses. Your eye drops contain a preservative which can be deposited on soft contact lenses. It is important that your lenses are removed before using your eye drops and not put back into your eyes for 15 minutes.

Tell your doctor before you have an operation that you are using **TILOPTIC** as timolol may change effects of some medicines used during anaesthesia.
If your eye becomes irritated or any new eye problems come on, talk to your doctor straight away. Eye problems could include redness of the eye or swelling of the eyelids (see Section 4 “SIDE EFFECTS”).
If you suspect that **TILOPTIC** is causing an allergic reaction or hypersensitivity (for example, skin rash, or redness and itching of the eye), stop using **TILOPTIC** and contact your doctor immediately.

Tell your doctor if:
- you have an eye infection
- you injured your eye or about to have an operation on it
- your eye problems get worse, or you have any new symptoms.

2.3 Taking other medicines
If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, you should tell the attending doctor or pharmacist.
ESPECIALLY INFORM YOUR DOCTOR OR PHARMACIST IF YOU ARE TAKING:
Other eye drops for the treatment of glaucoma or any other eye drops, medicine to lower blood pressure, heart medicines or medicines to treat diabetes.

It is important to tell your doctor before using **TILOPTIC** if you are taking one or more of the following medicines:
- a calcium antagonist, such as nifedipine, verapamil or diltiazem, often used to treat high blood pressure, angina, an abnormal heartbeat or Raynaud’s syndrome
- digoxin, a medicine used to relieve heart failure or treat abnormal heartbeat
- medicines known as catecholamine-depleting agents, such as rauwolfia alkaloids or reserpine, used for high blood pressure
- medicines called pressor amines, such as adrenaline used to treat severe allergic reaction
- quinidine (used to treat heart conditions and some types of malaria)
- antidepressants known as fluoxetine and paroxetine
- clonidine, a medicine used to treat high blood pressure
- other beta-blockers taken by mouth or used as eye drops, because they belong to the same group of medicines as **TILOPTIC** and could have an additive effect.

2.4 Pregnancy and breast-feeding
Consult your doctor or pharmacist before taking any medicine.

Use in pregnancy
Do not use **TILOPTIC** if you are pregnant unless your doctor considers it necessary.

Use in breast-feeding
Do not use **TILOPTIC** if you are breast-feeding. Timolol may get into your milk. Ask your doctor for advice before taking any medicine during breast-feeding.

2.5 Driving and using machines
There are possible side effects associated with **TILOPTIC**, such as dizziness, tiredness and changes in your eyesight, such as blurred vision, drooping of the upper eyelid (making the eye stay half closed), double vision which may affect your ability to drive and/or operate machinery. Do not drive and/or operate machinery until you feel well and your vision is clear.

2.6 Important information about some of the ingredients of TILOPTIC
TILOPTIC contains 0.01% benzalkonium chloride as a preservative; it may be deposited in soft contact lenses (See also section 2.2 “Special warnings concerning use of **TILOPTIC**”).

Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or disorders of the cornea (the transparent layer covering the front part of the eye). If you have unusual sensations in the eye after using the medicine, talk to your doctor.

This medicine contains the following phosphates:
• Disodium phosphate dodecahydrate (30.42 mg/ml per Tiloptic 0.5%)
• Sodium dihydrogen phosphate dihydrate (6.10 mg/ml per Tiloptic 0.5%)
If you have a significantly damaged cornea (the transparent layer covering the front part of the eye), in rare cases phosphates may cause cloudy cornea due to calcium buildup during the treatment.

3. HOW TO USE TILOPTIC

Always use **TILOPTIC** as instructed by the doctor. You should check with your doctor or pharmacist if you are not sure.
The dosage and duration of treatment will be determined by the doctor only.

The usually recommended dose is:

One drop in the affected eye(s) twice each day:

- one in the morning
- one in the evening

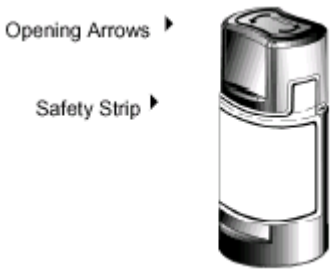
Do not exceed the recommended dose.
This medicine is intended for external use only.

Do not allow the tip of the container to touch the eye or areas around the eye. It may become contaminated with bacteria that can cause eye infection leading to serious damage of the eye, even loss of vision. To avoid possible contamination of the container, keep the tip of the container away from contact with any surface.

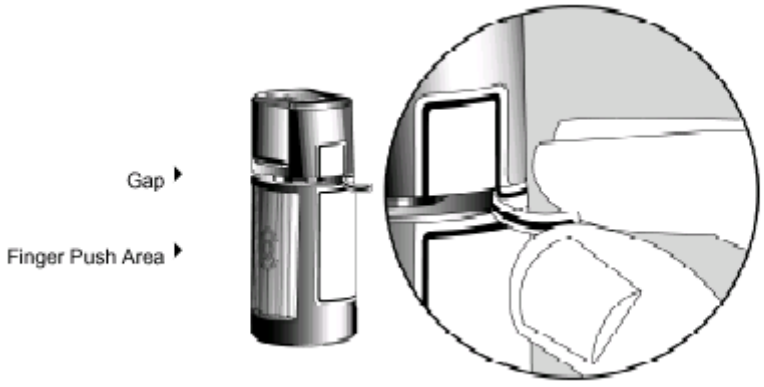
INSTRUCTIONS FOR USE

1. Before putting in your eye drops wash your hands thoroughly.

2. Before using the medication for the first time, be sure the Safety Strip on the front of the bottle is unbroken. A gap between the bottle and the cap is normal for an unopened bottle.



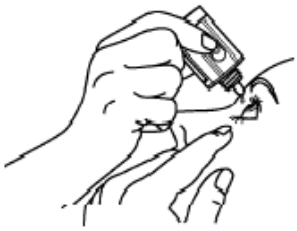
3. Tear off the Safety Strip to break the seal.

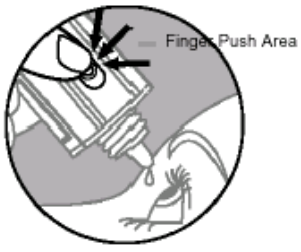


4. To open the bottle, unscrew the cap by turning as indicated by the arrows on the top of the cap. Do not pull the cap directly up and away from the bottle. Pulling the cap directly up will prevent your dispenser from operating properly.

5. Tilt your head back and pull your lower eyelid down slightly to form a pocket between your eyelid and your eye.

6. Invert the bottle and press lightly with the thumb or index finger over the “Finger Push Area” (as shown) until a single drop is dispensed into the eye as directed by your doctor. **DO NOT TOUCH YOUR EYE OR EYELID WITH THE DROPPER TIP.**





7. After using **TILOPTIC**, press a finger into the corner of your eye, by the nose for 2 minutes. This helps to stop timolol getting into the rest of your body and therefore helps to prevent side effects.

Ophthalmic medications, if handled improperly, can become contaminated by common bacteria known to cause infections. Serious damage to the eye and subsequent loss of vision may result from using contaminated ophthalmic medications. If you think your medication may be contaminated, or if you develop an eye infection, contact your doctor immediately concerning continued use of this bottle.

8. If drop dispensing is difficult after opening for the first time, replace the cap on the bottle and tighten (do not overtighten) and then remove by turning the cap in the opposite direction as indicated by the arrows on top of the cap.

9. Repeat steps 5, 6 and 7 with the other eye if instructed to do so by your doctor.

10. Replace the cap by turning until it is firmly touching the bottle. The arrow on the left side of the cap must be aligned with the arrow on the left side of the bottle label for proper closure. Do not overtighten the cap or you may damage the bottle and cap.

11. The dispenser tip is designed to provide a single pre-measured drop; therefore, do NOT enlarge the hole of the dispenser tip.

12. After you have used all the doses there may be some **TILOPTIC** left in the bottle. You should not be concerned since an extra amount of **TILOPTIC** has been added in order to ensure that you get the full amount of **TILOPTIC** that your doctor prescribed. Do not attempt to remove excess medicine from the bottle.

Do not bring the bottle within a direct contact with the eye or the area around the eye.

Examinations and monitoring
During treatment with this medicine, intraocular pressure tests should be performed.

Duration of treatment:
Your doctor will decide for how long the eye drops will be needed.

If you use more TILOPTIC than you should
If you put too many drops in your eye or swallow any of the drops, you may:
- have a headache
- feel dizzy or light-headed
- have difficulty breathing
- chest pain
- feel that your heart rate has slowed down.

If this happens, contact your doctor immediately.
If you have taken an overdose, or if a child has accidentally swallowed the medicine, proceed immediately to a hospital emergency room and bring the package of the medicine with you.

If you forget to take TILOPTIC
It is important to take **TILOPTIC** as prescribed by your doctor.
- If you miss a dose, use the drops as soon as possible.
- If it is almost time for the next dose, skip the missed dose and take the next dose at the usual time.
- Do not take a double dose to make up for the forgotten dose.

Complete the full course of treatment as instructed by the doctor.
Even if there is an improvement in your health, do not discontinue use of this medicine before consulting your doctor.

If you stop using TILOPTIC
If you want to stop using this medicine talk to your doctor first. If you have further questions about the medicine, ask your doctor or pharmacist.

How can you contribute to the success of the treatment?

1. In order to prevent infection make sure the dispenser tip does not come in contact with any surface (including the eye itself). The bottle should be kept well closed.
2. The bottle may be not completely full; this is in order to enable a better control on the dripping pace.
3. How to use the eye drops: See section **INSTRUCTIONS FOR USE.**
4. After using the medicine wash your hands thoroughly in order to clean them from medicine residues.
5. To prevent spreading contamination the same bottle must not be used for more than one person.

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

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

4. SIDE EFFECTS

Like all medicines, **TILOPTIC** can cause side effects, in some of the users.
Do not be alarmed by reading the list of side effects, you may not suffer from any of 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 **TILOPTIC** without speaking to your doctor.
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. Incidence of side effects after topical ophthalmic administration is lower than when medicines are, for example taken by mouth or injected. Listed side effects include reactions seen within the class of beta-blockers when used for treating eye conditions.

Stop using TILOPTIC and seek medical attention immediately, if you develop any of the following signs:

- allergic reactions including swelling beneath the skin that can occur in areas such as the face and limbs, and can obstruct the airway which may cause difficulty swallowing or breathing, hives or itchy rash, localized and generalized rash, itchiness, severe sudden life-threatening allergic reaction.

Additional side effects

- Low blood glucose levels.
- Difficulty sleeping (insomnia), depression, nightmares, memory loss, hallucinations.
- Fainting, stroke, reduced blood supply to the brain, increases in signs and symptoms of myasthenia gravis (muscle disorder), dizziness, unusual sensations like tingling or pins and needles, and headache.
- Signs and symptoms of eye irritation (e.g. burning, stinging, itching, tearing, redness), inflammation of the eyelid, inflammation in the cornea, blurred vision and detachment of the layer below the retina that contains blood vessels following filtration surgery which may cause visual disturbances, decreased corneal sensitivity, dry eyes, corneal erosion (damage to the front layer of the eyeball), drooping of the upper eyelid (making the eye stay half closed) double vision, sensitivity to light, discharge from the eye, pain in the eye if you have a significantly damaged cornea, which may be caused in rare cases by use of phosphates, cloudy cornea as a result of calcium buildup during the treatment.
- Ringing sound in the ears.
- Slow heart rate, chest pain, palpitations, oedema (fluid buildup), changes in the rhythm or speed of the heartbeat, congestive heart failure (heart disease with shortness of breath and swelling of the feet and legs due to fluid buildup), a type of heart rhythm disorder, heart attack, heart failure.

- Low blood pressure, fainting, interference with the blood supply to the brain which may lead to a stroke, Raynaud's phenomenon, cold hands and feet, limping because there is a reduced blood supply to your legs.
- Constriction of the airways in the lungs (predominantly in patients with pre-existing disease), difficulty breathing, shortness of breath, wheezing, cough.
- Taste disturbances, nausea, indigestion, diarrhoea, dry mouth, abdominal pain, vomiting.
- Sexual dysfunction, decreased sex drive, decreased libido. In men a condition which effects your penis called Peyronie's disease. The signs may be abnormal curve, pain or hardening of the tissue of your penis
- Hair loss, skin rash with white silvery coloured appearance (psoriasiform rash) or worsening of psoriasis, skin rash, itching.
- Muscle weakness/tiredness, muscle pain not caused by exercise .
- A condition called lupus (systemic lupus erythematosus).

If a side effect appears, if any of the side effects gets serious or if you suffer from a side effect not mentioned in this leaflet, consult your doctor.

Adverse events can be reported to the Ministry of Health by clicking on the link "Report on side effects following medicinal treatment" on the homepage of the Ministry of Health website (www.health.gov.il) which leads to an online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il

5. HOW TO STORE TILOPTIC

- **Avoid Poisoning!** This medicine, as all other medicine, must be stored in a safe place out of the reach of children and/or infants, in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor!
- Do not use **TILOPTIC** after the expiry date (exp. date) which is stated on the pack. The expiry date refers to the last day of the indicated month.
- **Storage conditions:** Store below 25°C. Do not Freeze. Protect from light. Do not use this medicine for more than 30 days after the bottle is first opened.
- 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

6.1 What TILOPTIC contains

In addition to the active ingredient the medicine also contains: Dibasic Sodium Phosphate, Monobasic Sodium Phosphate, Benzalkonium chloride, Sodium hydroxide, Water for injections.
See also section 2.6 "Important information about some of the ingredients of **TILOPTIC**".

6.2 What TILOPTIC looks like and contents of the pack

TILOPTIC is a clear colourless to light yellow sterile eye drops solution.
Pack size: 5 ml bottle.

Registration holder:
Rafa Laboratories Ltd., P.O. Box 405, Jerusalem 9100301.

Manufacturer: Fareva Mirabel, Clermont-Ferrand, France

Revised in April 2021 in accordance with the Ministry of Health directives.

Drug registration no. listed in the official registry of the Ministry of Health:
113.20.22175

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