**Patient Leaflet According to the Pharmacists' Regulations (Preparations) – 1986**
This medicine is sold with a doctor's prescription only

# Saflutan
Eye drops

Each ml contains:
Tafluprost 15 mcg

Each single-dose container (0.3 mL) contains:
Tafluprost 4.5 mcg

For the list of the inactive substances see Section 6.1 **"What Saflutan contains".**

**Read the entire leaflet carefully before using the medicine.**
- Keep this leaflet. You may need to read it again.
- This leaflet contains concise information about Saflutan. If you have further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for treatment for you. Do not pass it on to others. It may harm them, even if you think their medical condition is similar to yours.
- This medicine is not intended for children and adolescents under the age of 18.

## 1. What is Saflutan intended for?
Saflutan is used to treat a type of glaucoma called open-angle glaucoma and a condition known as ocular hypertension. Both these conditions are linked with an increase in the pressure within your eye and eventually they may affect your eyesight.

**Therapeutic Group**: **Saflutan** eye drops contain tafluprost, which belongs to a group of medicines called prostaglandin analogues.

## 2. Before using Saflutan
### 2.1 Do not use Saflutan if:
- You are allergic (hypersensitive) to tafluprost or any of the other ingredients of **Saflutan** (for the list of the inactive ingredients, see section 6.1).

### 2.2 Special warnings concerning the use of Saflutan
Talk to your doctor before using **Saflutan.**
**Please note** that **Saflutan** may have the following effects and that some of them may be permanent:
- **Saflutan** may increase the length, thickness, color and/or number of your eyelashes and may cause unusual hair growth on your eyelids.
- **Saflutan** may cause darkening of the color of the skin around the eyes. Wipe off any excess solution from the skin. This will reduce the risk of skin darkening.
- **Saflutan** may change the color of your iris (the colored part of your eye). If **Saflutan** is used in one eye only, the color of the treated eye may permanently become different from the color of the other eye.

**Before starting the treatment with Saflutan, tell your doctor:**
- If you have kidney problems
- If you have liver problems
- If you have asthma
- If you have other eye diseases

**2.3 Taking other medicines**
**If you are taking or have recently taken any other medicines, including non-prescription medicines and nutritional supplements, please tell your doctor or pharmacist.**
If you use other medicines **in the eye**, wait at least 5 minutes between putting in **Saflutan** and putting in the other medication.

**2.4 Pregnancy, breastfeeding and fertility**
Do not use **Saflutan** if you are pregnant. If you may become pregnant, you must use an effective method of birth control during **Saflutan** therapy.
Do not use **Saflutan** if you are breastfeeding. Ask your doctor for advice.

**2.5 Driving and use of machinery**
**Saflutan** has minor influence on the ability to drive and operate machinery. You may find that your vision is blurred for a time after you put **Saflutan** in your eye. Do not drive or use any tools or machines until your vision is clear.

**2.6 Use in children and adolescents**
**Saflutan** is not recommended for children and adolescents under the age of 18 years due to a lack of data on safety and efficacy.

2.7 **Saflutan contains phosphates**
This preparation contains approximately 0.04 mg phosphates in each drop which is equivalent to 1.2 mg/ml. If you suffer from severe damage to the cornea (the clear layer at the front of the eye), phosphates may cause in very rare cases cloudy patches on the cornea due to calcium buildup during treatment.

## 3. How to use Saflutan?
Always use **Saflutan** according to the doctor's instructions. 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 standard dosage is usually:**
1 drop of **Saflutan** in the eye or eyes, once daily in the evening.
Do not instill more drops or use more often than instructed by your doctor. This may make **Saflutan** less effective.
Only use **Saflutan** in both eyes if your doctor told you to.
This medicine is intended for use as eye drops only. Do not swallow.
**Do not exceed the recommended dose.**
This medicine is intended for external use only.

## Instructions for use
<u>When you start a new aluminum pouch:</u>
Do not use the single-dose containers if the aluminum pouch is torn. Open the pouch along the dotted line. Write down the date on which you opened the pouch in the place intended for the date on the pouch.

<u>Each time you use **Saflutan**</u>:

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| 1. Wash your hands.<br>2. Remove the strip of containers from the aluminum pouch.<br>3. Remove one of the single-dose containers from the strip.<br>4. Return the rest of the strip to the pouch and fold the edge of the pouch in order to close it.<br>5. Check that the solution is in the bottom part of |  |

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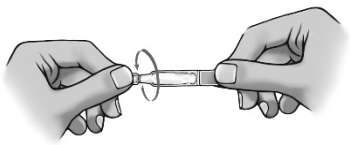
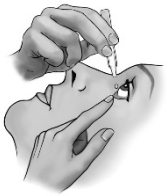
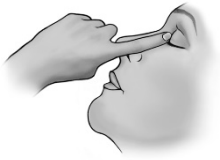
| the single-dose container | |
| 6. To open the container turn the tab. |  |
| 7. Tilt your head backwards.<br>8. Place the edge of the container close to your eye. |  |
| 9. Pull the lower eyelid downwards and look up.<br>10. Gently squeeze the container and allow one drop to fall into the space between the lower eyelid and the eye. |  |
| 11. Close the eye and press the inner corner of the eye with your finger for about one minute. This helps prevent the eye drop from draining down your tear duct and being absorbed in the rest of your body, and this helps prevent side effects.<br>12. Wipe off any excess solution from the skin around the eye. |  |

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**If the drop missed the eye**, try again.
**If your doctor instructed you to use drops in both eyes**, repeat stages 7 to 12 for the second eye. The contents of one single-dose container suffice for both eyes. Discard the open single-dose container with the rest of the solution immediately after use.

**If you use other medicine**s **in the eye**, wait at least 5 minutes between putting in **Saflutan** and putting in the other medications.

**If you used more Saflutan than you should**
It is unlikely to cause you any serious harm. Contact your doctor, but do not stop taking the medicine. Put in the next dose at the usual time.
If you accidentally swallowed the medicine, please contact a doctor for advice.
If someone accidentally swallowed the medicine, proceed immediately to a hospital emergency room and bring the package of the medicine with you.

**If you forgot to take Saflutan**
Use a single drop as soon as you remember, and then go back to your regular routine. Do not use a double dose to compensate for the forgotten dose.
Complete the entire course of treatment as recommended by your doctor.
Even if your state of health improves, do not stop the treatment with this medicine without consulting your doctor.

**Do not stop using Saflutan without consulting your doctor. If you stop using Saflutan**, the pressure in the eye will increase again. This may cause a permanent injury to your eye.

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

**How can you contribute to the success of the treatment?**
1. To prevent infection make sure that the end of the single-dose container does not come into contact with any surface (including the actual eye).
2. How to use the eye drops: see "**Instructions for use**" section.
3. After using the medicine, wash your hands well to clean them of residues of the medicine.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine.
Wear glasses if you need them.
If you have further questions about the use of the medicine, ask your doctor or pharmacist.

## 4. Side effects
Like any medicine, the use of Saflutan may cause side effects in some users.
Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

**Common side effects**
The following may affect up to 1 in 10 people:
Effects on the nervous system
- Headache

Effects on the eye:
- Itching of the eye
- Irritation of the eye
- Eye pain
- Redness of the eye
- Changes in the length, thickness and number of eyelashes
- Dry eye
- Foreign body sensation in eye

- Discoloration of eyelashes
- Redness of the eyelids
- Small spotlike areas of inflammation on the surface of the eye
- Sensitivity to light
- Watery eyes
- Blurred vision
- Reduction in the eye's ability to see details
- Change of color of the iris (may be permanent)

**Uncommon side effects**
The following may affect up to 1 in 100 people:
Effects on the eye:
- Change of color of the skin around the eyes
- Puffy eyelids
- Tired eyes
- Swelling of the eye's surface membranes
- Eye discharge
- Inflammation of the eyelids
- Signs of inflammation inside the eye
- Discomfort in the eye
- Pigmentation of the eye's surface membranes
- Follicles in the eye's surface membranes
- Allergic inflammation
- Abnormal sensation in the eye

Effects on the skin and tissue under the skin:
- Unusual hair growth on eyelids

**Side effects of unknown frequency (cannot be estimated from the available data):**
Effects on the eye:
- Inflammation of the iris/uvea (middle layer of the eye)
- Eyes appear sunken
- Swelling of the retina
- If you suffer from severe damage to the cornea (the clear layer at the front of the eye), phosphates may cause in very rare cases cloudy patches on the cornea due to calcium buildup during treatment.

Effects on the respiratory system:
- Worsening of asthma, shortness of breath

In very rare cases, patients suffering from severe damage to the clear layer at the front of the eye (cornea) have developed cloudy patches on the retina, as a result of calcium buildup during the treatment.

If side effects have appeared, if one of the side effects becomes worse or if you suffer from a side effect not indicated in this leaflet, please consult with your doctor.

Side effects may 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 Saflutan?

Avoid poisoning! This medicine, like any other medicine, must be stored in a safe place out of the reach and sight of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.

- Do not use Saflutan after the expiry date (exp. date) stated on the package. The expiry date refers to the last day of the month indicated.
- **Storage conditions:**
  Store the closed aluminum pouch in the refrigerator (at a temperature of 2°C - 8°C). Do not open the container until the first use, since 28 days after the first opening of the pouch the containers that were in the open pouch must be discarded and will not be used.
  After opening the aluminum pouch:
  - Store the single-dose containers in the original aluminum pouch.
  - Do not store above 25°C.
  - Discard unused single-dose containers after 28 days from the first opening of the aluminum pouch.
  - Discard the open single-dose container with the rest of the solution immediately after use.
- Do not throw medicines into the wastewater or household waste bin. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## 6. Additional information

### 6.1 What does Saflutan contain?

- The active ingredient is: tafluprost. 1 ml of solution contains 15 mcg tafluprost. One single-dose container (0.3 mL) contains about 4.5 mcg tafluprost. One drop (about 30 mcl) contains about 0.45 mcg tafluprost.
- In addition to the active ingredients, the medicine also contains inactive ingredients:

glycerol, sodium dihydrogen phosphate dihydrate, polysorbate 80, disodium edetate, hydrochloric acid and/or sodium hydroxide, and purified water.

### 6.2 What Saflutan looks like and contents of the pack

**Saflutan** - a clear, colorless liquid (solution), marketed in single-dose plastic containers, each containing 0.3 mL solution. There are 10 single-dose containers in one aluminum pouch.
Pack size: **Saflutan** comes in packs containing 30 or 90 single-dose containers.
Not all package sizes may be marketed.

**Registration holder:**
Rafa Laboratories Ltd., PO Box 405, Jerusalem 9100301

**Manufacturer:**
Merck Sharp & Dohme B.V., Haarlem, The Netherlands

**Medicine registration number in the National Medicines Registry of the Ministry of Health:**
146-96-33302

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