

Package leaflet: Information for the patient
Saflutan 15 micrograms/ml
eye drops, solution
Tafluprost

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms of illness 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 Saflutan is and what it is used for
2. What you need to know before you use Saflutan
3. How to use Saflutan
4. Possible side effects
5. How to store Saflutan
6. Contents of the pack and other information

1. What Saflutan is and what it is used for

What kind of medicine is it and how does it work?

Saflutan eye drops contain tafluprost, which belongs to a group of medicines called prostaglandin analogues. Saflutan lowers the pressure in the eye. It is used when the pressure in the eye is too high.

What is your medicine for?

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

2. What you need to know before you use Saflutan

Do not use Saflutan

- if you are allergic to tafluprost or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor, pharmacist or nurse 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, colour and/or number of your eyelashes and may cause unusual hair growth on your eyelids.
- Saflutan may cause darkening of the colour 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 colour of your iris (the coloured part of your eye). If Saflutan is used in one eye only, the colour of the treated eye may permanently become different from the colour of the other eye.
- Saflutan may cause hair growth in areas where the solution comes repeatedly in contact with the skin surface.

Tell your doctor

- if you have kidney problems
- if you have liver problems
- if you have asthma
- if you have other eye diseases.

Children and adolescents

Saflutan is not recommended for children and adolescents below 18 years due to a lack of data on safety and efficacy.

Other medicines and Saflutan

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

If you use other medicines **in the eye**, leave at least 5 minutes between putting in Saflutan and the other medication.

Pregnancy, breast-feeding and fertility

If you may become pregnant, you must use an effective method of birth control during Saflutan therapy. Do not use Saflutan if you are pregnant. You should not use Saflutan if you are breast-feeding. Ask your doctor for advice.

Driving and using machines

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

Saflutan contains phosphates

This medicine 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 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.

3. How to use Saflutan

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

The recommended dose is 1 drop of Saflutan in the eye or eyes, once daily in the evening. Do not instil more drops or use more often than as instructed by your doctor. This may make Saflutan less effective.

Only use Saflutan in both eyes if your doctor told you to.

For use as eye drops only. Do not swallow.

Instructions for use:

When using for the first time, before delivering a drop to the eye, you should first of all practise using the bottle by squeezing it slowly to deliver one drop away from the eye.

When you are confident that you can deliver one drop at a time, choose the position that you find most comfortable for the instillation of the drops (you can sit down, lie on your back, or stand in front of a mirror).

When you start a new bottle:

Do not use the bottle if the plastic ring around the bottle neck is missing or broken. Write down the date you opened the bottle in the space reserved for the date on the outer carton.

Every time you use Saflutan:

1. Wash your hands.
2. When you are using the bottle for the first time, remove the tamper-evident ring of the cap by pulling the tab



3. Open the bottle by pulling the cap.
4. When **using the bottle the first time**, drop one drop to waste.

5. Hold the bottle between your thumb and middle finger.



6. Tilt your head backwards or lie down. Place your hand on your forehead. Your index finger should be aligned with your eyebrow or resting on the bridge of the nose. Take special care that the tip of the dropper bottle does not touch your eye, the skin around your eye or your fingers to prevent potential contamination of the solution.

7. Pull the lower eyelid downwards with the other hand and look up. Gently squeeze the bottle and let one drop fall into the space between the lower eyelid and the eye. Please note that there might be a slight delay between squeezing and the drop coming out. Do not squeeze too hard.



8. Close the eye and press the inner corner of the eye with your finger for about one minute. Thus you can prevent the eye drop from draining down the tear duct.



9. Wipe off any excess solution from the skin around the eye to reduce the risk of darkening of the eyelid skin.

10. Shake the bottle once downwards to get rid of any remaining solution from the top. Do not touch or wipe the top.
11. Put the cap back on and close the bottle



tightly.

There will be a residual volume of approximately 1 ml, which cannot be dosed. Do not try to empty the bottle.

If a drop misses your eye, try again.

If your doctor has told you to use drops in both eyes, repeat steps 6 to 9 for your other eye.

If you use other medicines in the eye, leave at least 5 minutes between putting in Saflutan and the other medication.

If you use more Saflutan than you should, it is unlikely to cause you any serious harm. Put in your next dose at the usual time.

If the medicine is accidentally swallowed, please contact a doctor for advice.

If you forget to use 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 make up for a forgotten dose.

Do not stop using Saflutan without asking 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 any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Most side effects are not serious.

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 in the eye
- eye pain
- redness of the eye
- changes in the length, thickness and number of eyelashes
- dry eye
- foreign body sensation in the eye
- discolouration 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 colour 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 colour 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 surface membranes of the eye
- allergic inflammation
- abnormal sensation in the eye.

Effects on the skin and tissue under the skin:

- unusual hair growth on eyelids.

Not known: 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
- macular oedema/cystoid macular oedema (swelling of the retina within the eye leading to worsening vision).

Effects on the respiratory system:

- worsening of asthma, shortness of breath.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom: Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Ireland: HPRA Pharmacovigilance, Website: www.hpra.ie.

5. How to store Saflutan

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the bottle label and the outer carton after 'Exp'. The expiry date refers to the last day of that month.

Store in the refrigerator (2°C – 8°C). Do not freeze.

After opening, store below 25°C.

Store in the original carton in order to protect from light.

You must throw away the bottle 3 months after you first opened it, to prevent infections, and use a new bottle. The bottle with 3 ml fill volume is intended for 1 month in-use period, 5 ml fill volume bottle for 2 months and 7 ml fill volume bottle for 3 months.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Saflutan contains

- **The active substance** is tafluprost. 1 ml of solution contains 15 micrograms of tafluprost. One drop contains about 0.45 micrograms of tafluprost.

- **The other ingredients** are glycerol, sodium dihydrogen phosphate dihydrate, disodium edetate, polysorbate 80, and water for injections. Hydrochloric acid and/or sodium hydroxide are added to adjust the pH.

What Saflutan looks like and contents of the pack

Saflutan is a clear, colourless liquid (solution), practically free from visible particles. It is supplied in a pack containing either 1 transparent plastic bottle with 3 ml, 5 ml or 7 ml, or 3 transparent plastic bottles with 3 ml solution each. The plastic bottles are closed with caps. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Santen Oy
Niittyhaankatu 20
33720 Tampere
FINLAND

Manufacturer

Santen Oy
Kelloportinkatu 1
33100 Tampere
FINLAND

Tubilux Pharma SpA
Via Costarica 20/22
00071 Pomezia (Roma)
Italy

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

TAFLOTAN sine: Germany

Taflotan sine: Denmark, Finland, Iceland, Norway, Sweden

Taflotan: Bulgaria, Cyprus, Czech Republic, Estonia, Greece, Hungary, Latvia, Lithuania, Portugal, Slovak Republic, Spain

Taflotan Multi: Poland

Saflutan: Austria, Belgium, Croatia, Ireland, Luxembourg, The Netherlands, Romania, Slovenia, United Kingdom (Northern Ireland)

Safluround: Italy

This leaflet was last revised in 07/2022

Detailed information on this medicine is available on the web site of Medicines & Healthcare products Regulatory Agency (MHRA), www.mhra.gov.uk. Health Products Regulatory Authority (HPRA), www.hpra.ie.