

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about SAFLUTAN.
It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.
All medicines have risks and benefits. Your doctor or pharmacist has weighed the risks of you using SAFLUTAN against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.
Keep this leaflet with the medicine.

You may need to read it again.

What SAFLUTAN is used for

SAFLUTAN belongs to a group of medicines called prostaglandin analogues. It is used to lower raised pressure in the eye and to treat glaucoma. Glaucoma is a condition in which the pressure of fluid in the eye may be high. However, some people with glaucoma may have normal eye pressure. Also, some people with raised eye pressure may not have glaucoma.

Glaucoma is usually caused by a build-up of the fluid which flows through the eye. This build up occurs because the fluid drains out of your eye more slowly than it is being pumped in. Since new fluid continues to enter the eye, joining the fluid already there, the pressure continues to rise. This raised pressure may damage the back of the eye resulting in gradual loss of sight. Damage can progress so slowly that the person is not aware of this gradual loss of sight. Sometimes even normal eye pressure is associated with damage to the back of the eye. There are usually no symptoms of glaucoma. The only way of knowing that you have glaucoma is to have your eye pressure, optic nerve and visual field checked by an eye specialist or optometrist. If glaucoma is not treated it can lead to serious problems, including total blindness. In fact, untreated glaucoma is one of the most common causes of blindness.

Although SAFLUTAN helps control your glaucoma it does not cure it so you must keep using SAFLUTAN until your doctor tells you to stop.

SAFLUTAN lowers pressure in the eye by allowing more fluid to flow out from within your eye.

SAFLUTAN is used, either alone or in combination with other eye drops or medicines, to lower raised pressure within your eye(s).

SAFLUTAN is not addictive.

Before you use SAFLUTAN

When you must not use it

Do not use SAFLUTAN if:

- You have an allergy to tafuprost or any of the ingredients listed at the end of this leaflet.
- The packaging shows signs of tampering
- The expiry date (EXP) printed on the pack has passed.

If you use this medicine after the expiry date has passed, it may not work.

If you are not sure whether you should start using/taking SAFLUTAN, talk to your doctor.

The safety and effectiveness of SAFLUTAN in children have not been established. SAFLUTAN is not recommended for use in children.

Before you start to use it

Tell your doctor or pharmacist if you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes

Tell your doctor or pharmacist if you are pregnant or intend to become pregnant.

If you are a woman of childbearing age, you should use an effective method of birth control when using SAFLUTAN.

If you become pregnant, talk to your doctor immediately to determine if you should use SAFLUTAN.

Tell your doctor or pharmacist if you are breast-feeding or plan to breast-feed.

Your doctor or pharmacist will discuss the possible risks and benefits of using SAFLUTAN during breastfeeding.

Tell your doctor or pharmacist if you have or have had any medical conditions, especially the following:

- other eye diseases
- kidney disease
- liver disease
- lung disease, including asthma, chronic obstructive lung disease or other breathing problems.

If you have not told your doctor or pharmacist about any of the above, tell them before you start using SAFLUTAN.

You may experience the following side effects, some of which may be permanent. These effects may occur slowly and it may be several months before you notice them. SAFLUTAN may:

- increase the length, thickness, colour and/or number of your eyelashes and may cause unusual hair growth around your eyelids
- 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.
- 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.

Taking other medicines

Tell your doctor or pharmacist if you are taking or using any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

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

How to use SAFLUTAN

Use SAFLUTAN only when prescribed by your doctor.

Follow all directions given to you by your doctor carefully.

How much to use

The dose is one drop of SAFLUTAN in the eye or eyes, once daily in the evening. Only use SAFLUTAN in both eyes if your doctor has told you to do so.

Do not instil more drops or use more often than as instructed by your doctor.

This may make SAFLUTAN less effective.

Do not stop using SAFLUTAN without asking your doctor.

If you stop using SAFLUTAN, the pressure in the eye will increase again. This may result in permanent damage to the eye.

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

Follow all directions given to you by your doctor and pharmacist carefully.

These directions may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

If you are being changed from one eye drop to another, follow your doctor's instructions carefully as to when to stop the old drops and when to start the new drops.

How to use it

You may find it easier to put eye drops in your eye while you are sitting or lying down.

If you are wearing soft contact lenses, remove them before putting the drops in your eye.

When starting a new pouch:

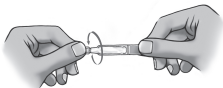
Do not use the single-dose containers if the pouch is broken. Open the pouch along the dotted line. Write the date of opening on the space reserved for this on the pouch.

When using SAFLUTAN:

1. Wash your hands well with soap and water
2. Take the strip of containers from the pouch
3. Detach one single dose container from the strip
4. Put the remaining strip back in the pouch and fold down the edge to close the pouch
5. Make sure that the solution is in the bottom part of the single-dose container



6. To open the container, twist off the tab



7. Tilt your head backwards. If you are unable to tilt your head, lie down.

8. Place the tip of the container close to your eye. Be careful not to touch the tip of the container to the eye itself.



9. Pull the lower eye lid downwards and look up.

10. Gently squeeze the container and let one drop fall into the space between the lower eyelid and the eye



11. Close your eye for a moment and press the inner corner of the eye with your finger for about one minute.

This helps prevent the eye drop from draining down the tear duct. Do not blink or rub your eye.



12. Blot off any excess solution from the skin around the eye with a tissue

If a drop misses your eye, try again.

If your doctor has told you to use drops in both eyes, repeat steps 7 to 12 for your other eye.

The contents of one single-dose container of SAFLUTAN are sufficient for both eyes. After dosing, discard the single-dose container even if there is solution remaining. Wash your hands with soap and water to remove any residue.

If you are not sure how to use eye drops, ask your doctor or pharmacist.

If you are not sure what to do, ask your doctor or pharmacist.

How long to use it

SAFLUTAN helps control your condition, but does not cure it. Therefore you must use SAFLUTAN every day.

Do not stop using it unless your doctor or pharmacist tells you to stop.

If you forget to use it

If it is almost time for your next dose, skip the dose you missed and use your next dose when you are meant to.

Otherwise, use it as soon as you remember, and then go back to using your medicine as you would normally at the usual time.

Do not use a double dose to make up for the dose that you missed.

If you have trouble remembering to use your eye drops, ask your pharmacist for some hints.

If you use too much (overdose)

If you accidentally put several drops in your eye(s), immediately rinse your eye(s) with warm water.

If you think that you or anyone else may have swallowed any or all of the contents of a single-dose container of SAFLUTAN immediately telephone your doctor or pharmacist or the Poisons Information Centre or go to accident and emergency at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning.

While you are using SAFLUTAN

Things you must do

Have your eye pressure checked when your eye specialist says, to make sure SAFLUTAN is working.

If you develop an eye infection, receive an eye injury, or have eye surgery, tell your doctor.

Your doctor may advise you to stop your treatment with SAFLUTAN.

If you become pregnant while using SAFLUTAN, tell your doctor immediately.

After opening a single-dose container of SAFLUTAN, immediately use it in one or both eyes and then discard the single-dose container, even if there is some solution remaining.

SAFLUTAN does not contain any preservatives. Therefore, if you keep the remaining solution for your next dose, there is a risk that it may be contaminated with germs and cause an eye infection.

Tell any other doctors, dentists, and pharmacists who are treating you that you are using SAFLUTAN.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are using SAFLUTAN.

Things you must not do

Do not give SAFLUTAN to anyone else, even if they have the same condition as you.

Do not give SAFLUTAN to a child under 18 years.

The safety and effectiveness of SAFLUTAN in children have not been established. SAFLUTAN is not recommended for use in children.

Do not stop using SAFLUTAN without first talking to your doctor or pharmacist.

If you stop using your eye drops, your eye pressures may rise again and damage to your eye may occur.

Things to be careful of

Be careful driving or operating machinery until you know how SAFLUTAN affects you.

SAFLUTAN generally does not cause any problems with your ability to drive a car or operate machinery. However, SAFLUTAN may cause blurred vision in some people. Make sure you know how you react to SAFLUTAN or that your vision is clear before driving a car or operating machinery.

Side effects

Check with your doctor as soon as possible if you have any problems while using SAFLUTAN, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

SAFLUTAN helps most people with glaucoma, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- redness, itching, or irritation of the eye(s)
- eye pain
- feeling that something is in the eye(s)
- dry eye
- watery eye(s) or eye discharge
- Redness or puffy eyelid(s)
- blurred vision or sharpness of your vision reduced
- sensitivity to light
- headache
- cataract

Patients also experience the following side effects:

- Change of colour of the iris (may be permanent)
- Changes in the length, thickness, or number of eyelashes, discolouration of eyelashes
- Change in the colour of the skin around the eye
- Deepening of the eye-lid crease (eyes appear sunken)
- Worsening of asthma
- Shortness of breath

These are the more common side effects seen in studies of SAFLUTAN. Mostly these are mild and short-lived.

Other side effects not listed above may occur in some patients. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After using SAFLUTAN

Storage

Keep your unopened single-dose containers in the foil pouch and store them at (2°C - 8°C). Refrigerate. Do not freeze. Do not open the pouch until you are about to start using the eye drops.

Do not store the eye drops out of the foil pouches.

- After opening the foil pouch:
- Keep the remaining single-dose containers in the original foil pouch
- Do not store above 25°C.
- Discard unused single-dose containers after 28 days from date of first opening the foil pouch.
- Discard any opened single-dose containers with any remaining solution immediately after use

Do not store SAFLUTAN or any other medicine in the bathroom or near a sink.

Do not leave it in the car on hot days or on window sills.

Do not carry the eye drops in pockets of your clothes.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

Do not use this medicine after the expiry date stated on the single-dose container, pouch and the outer carton.

If your doctor or pharmacist tells you to stop using SAFLUTAN, or it has passed its expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

SAFLUTAN is a clear, colourless liquid (solution) supplied in single-dose plastic containers, each containing 0.3mL of solution. Ten (10) single-dose containers are provided in one foil pouch.

Ingredients

Active ingredient:

The active ingredient in SAFLUTAN is tafuprost. Each single-dose container (0.3 mL) contains 4.5 micrograms of tafuprost.

Inactive ingredients:

- glycerol
- monobasic sodium phosphate dihydrate
- disodium edetate
- polysorbate 80
- hydrochloric acid and/or sodium hydroxide (to adjust pH)
- Water for injections

Marketing Authorization Holder :

Mundipharma Pty Limited, located at 88 Phillip Street, Sydney, NSW 2000 Australia

Manufacturer:

Laboratoire Unither, ZI de la Guerie, F-50211 Coutances Cedex, France

This leaflet was prepared in April 2016