

(Preservative-free single-unit dose vial)

Composition:

Taflan SUD Preservative-free Ophthalmic Solution: Each ml contains Tafluprost INN 0.015 mg. Pharmacology:

Tafluprost is a selective FP prostanoid receptor agonist which reduces intraocular pressure by increasing uveoscleral outflow as well as to a lesser degree through the trabecular outflow pathway. Tafluprost also relaxes ciliary artery in smooth muscle due to inhibition of Ca2+ influx into the cells. Hence, Tafluprost increases ocular blood flow and thus provides neuroprotective action.

Indications:

Taflan SUD Preservative-free Ophthalmic Solution is indicated for reducing elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension.

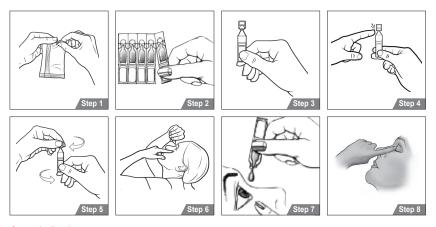
Dosage and Administration:

Instill one drop in the affected $\ensuremath{\mathsf{eye}}(s)$ once daily in the evening.

How to use Taflan SUD Preservative-free Ophthalmic Solution: Always use Taflan SUD Ophthalmic Solution as described in this leaflet or as directed by the physician. Make sure that the single-unit dose vial is intact before use. The solution should be used immediately after opening. The contents of one single-unit dose vial are sufficient for both eyes. Apply Taflan SUD

Preservative-free Ophthalmic Solution in the following way (Steps 1 to 8 pictures below)

- Step 1: Take a pillow pack out of the Taflan SUD box. Open the pillow pack and remove the strip of single-unit dose vial.
- Step 2: Pull off one single-unit dose vial from the strip. Put the remaining strip of single-unit dose vials back in the pillow pack
- **Step 3:** Hold the Taflan SUD vial upright.
- Step 4: Tap the top of the vial until all of the solution is in the bottom part of the vial.
- Step 5: Open the Taflan SUD single-unit dose vial by twisting off the cap. Make sure that the tip of the single-unit dose vial does not touch anything, to avoid contamination.
- Step 6: Tilt your head backwards. If you are not able to tilt your head, lie down. Gently pull your lower eyelid downwards and look up.
- Step 7: Place the tip of the Taflan SUD single-unit dose vial close to your eye, but be careful not to touch your eye with it. Gently squeeze the single-unit dose vial and let one drop of Taflan SUD Preservative-free Ophthalmic Solution fall inside the lower eyelid.
- Step 8: Close your eye for a moment. Press the inner corner of the eye with your index finger for about one minute.



Contraindications:

Contraindicated in patients who are hypersensitive to any of the components of this preparation. Side-effects:

Since Tafluprost is PRESERVATIVE-FREE, it avoids the potential risks caused by the preservatives. **Precaution:**

- For ophthalmic use only.
- Wash your hands before use.
- To avoid contamination or possible eye injury, do not let the open end of the single-unit dose vial touch your eye or anything else.
- If you wear contact lenses take out your lenses before using Ophthalmic Solution and then wait
- for at least 15 minutes after using this drops before putting your lenses back in.
 If more than one topical ophthalmic drug is being used, the drugs should be administered at least five (5) minutes between applications.

Use in special group:

Use in pregnancy: There are no adequate and well-controlled studies in pregnant women. Tafluprost ophthalmic solution should be used during pregnancy unless the potential benefit justifies the potential risk to the fetus.

Use in lactation: It is not known whether Tafluprost is excreted in human milk. Caution should be exercised while giving this ophthalmic solution to a nursing mother. **Use in children:** Safety and effectiveness have not been demonstrated with this Ophthalmic Solution in

pediatric patients. Use in elderly patients: No overall differences in safety or effectiveness have been observed between elderly and younger adult patients.

Storage:

- Keep unopened vial at 2 8°C. After opening keep the vial in a cool & dry place below 25°C.
- Discard the opened vial immediately after use.
- Keep out of the reach of children.

Packing:

Taflan SUD Preservative-free Ophthalmic Solution: Each Alu-Alu pillow pack contains 5 single-unit dose vials (SUD's). Each single-unit dose vial contains 0.2 ml of Ophthalmic Solution.





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