

(Preservative-free single-unit dose vial)

Composition:

Systear® SUD Preservative-free Eye Drops: Each ml contains Polyethylene Glycol 400 USP 4 mg & Propylene Glycol USP 3 mg.

Pharmacology:

The combination of Polyethylene Glycol 400 & Propylene Glycol is clinically proven to reduce both signs and symptoms of dry eye. The mechanism of action is thought to be due to its unique gelling and lubricating system formulated to adjust to each user's individual tear pH. When the ingredients of Systear® combine with natural tears, a soft gel forms a network of protection over the eye surface. Since it promotes a healthy environment in eye surface, damaged surface cells of eye can repair more easily.

Indications:

Systear® SUD Preservative-free Eye Drops is indicated for the temporary relief of burning and irritation due to dryness of the eye.

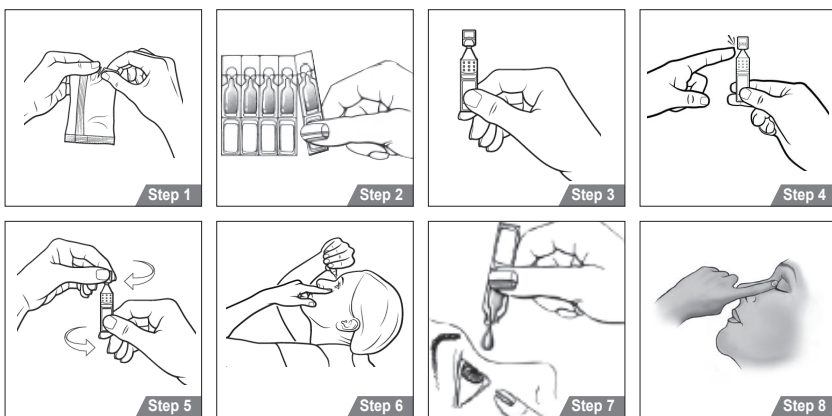
Dosage and Administration:

Instill 1 or 2 drops in the affected eye(s) as needed.

How to use Systear® SUD Preservative-free eye Drops:

Always use Systear® SUD eye drops 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 Systear® SUD Preservative-free eye drops in the following way (Steps 1 to 8 pictures below)

- Step 1:** Take a pillow pack out of the Systear® 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-use vials back in the pillow pack
- Step 3:** Hold the Systear® 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 Systear® 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 Systear® 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 Systear® SUD Preservative-free eye drops 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 Polyethylene Glycol & Propylene Glycol 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 eye drops 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. Polyethylene Glycol & Propylene Glycol Eye Drops should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Use in lactation: There are no adequate and well-controlled studies in lactating women. Caution should be exercised when Polyethylene Glycol & Propylene Glycol Eye Drops is administered to a nursing mother.

Use in children: Safety and effectiveness have not been demonstrated with this eye drops in pediatric patients.

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

Storage:

- Store below 30°C temperature in a dry place, protect from light.
- Discard after 12 hours of opening.
- Keep out of the reach of children.

Packing:

Systear® SUD Preservative-free Eye Drops: Each Alu-Alu pillow pack contains 5 single-unit dose vials (SUD's). Each single-unit dose vial contains 0.4 ml of eye drops.