



Fort Worth, Texas 76134, Mj.

MATTE COATING = No greater than 25 gloss units as measured by BYK-Gardner Micro-Gloss 60° gloss meter or similar device.

Systane™
ULTRA UD
LUBRICANT EYE DROPS
Preservative-Free

INSTRUCTIONS FOR USE

EN This Instructions For Use (IFU) leaflet contains important product use and safety information. Please read carefully and keep this for future use

PRODUCT NAME:
SYSTANE™ ULTRA UD Lubricant Eye Drops

DESCRIPTION:
SYSTANE™ ULTRA UD Lubricant Eye Drops is a sterile, **preservative-free** solution containing hydroxypropyl guar, polyethylene glycol 400, boric acid, propylene glycol, sorbitol, potassium chloride, sodium chloride, aminomethylpropanol, and purified water. May contain hydrochloric acid and/or sodium hydroxide to adjust pH.

CLINICAL BENEFITS:
SYSTANE™ ULTRA UD Lubricant Eye Drops is a preservative-free formulation which lubricates the eye surface to provide dry eye symptom relief and eye surface protection. Additionally, SYSTANE™ ULTRA UD Lubricant Eye Drops provides temporary relief from dryness related to contact lens wear.

INTENDED PURPOSE/USE:
SYSTANE™ ULTRA UD Lubricant Eye Drops is intended to lubricate the eye surface and wet soft contact lenses (including silicone hydrogel lenses).

INTENDED USERS/TARGET POPULATION:
Adults (18 years and older) experiencing dry eye symptoms, including contact lens wearers, who are capable of understanding and following the directions and instructions for use (or have a caregiver who can act on their behalf).

INDICATION (Uses):
SYSTANE™ ULTRA UD Lubricant Eye Drops is indicated for the temporary relief of burning and irritation in persons experiencing dry eye symptoms.

PERFORMANCE CHARACTERISTICS:
Based on the total body of evidence from clinical investigations, published clinical literature and market experience (post market surveillance), SYSTANE™ ULTRA UD Lubricant Eye Drops perform as indicated for the temporary relief of burning and irritation in persons experiencing dry eye symptoms.

DIRECTIONS:
• SYSTANE™ ULTRA UD Lubricant Eye Drops may be used as needed throughout the day to relieve the symptoms of dry eye.
• Twist off the top of the single dose vial, instill 1 or 2 drops in the affected eye(s) as needed and blink.
• While wearing contact lenses, if minor irritation, discomfort, or blurring occurs, instill 1 or 2 drops in the affected eye(s) and blink 2 or 3 times.
• **Discard the vial after use** into household waste or preferable into a plastic recycling bin, according to local waste management guidance.

CONTRAINDICATIONS /Reasons not to use:
People allergic to any ingredient in SYSTANE™ ULTRA UD Lubricant Eye Drops should not use this product.

WARNINGS:
It is essential that you follow your eye care professional's directions and all labeling instructions for proper use of the product. If you experience persistent eye discomfort, eye pain, excessive tearing, vision changes, or redness of the eye, stop using SYSTANE™ ULTRA UD Lubricant Eye Drops and consult your eye care professional as the problem could become more serious.

Temporary blurred vision or other visual disturbances may affect the ability to drive or use machines. If blurred vision occurs after application, wait until the vision clears before driving or using machinery.

PRECAUTIONS:
• For ocular use only.
• **TAMPER EVIDENT:** Do not use if package or unit dose vials (sterile packaging) are damaged or unintentionally opened before use. Product can be contaminated and lead to a serious eye infection.
• To avoid contamination, never touch the dropper tip of the vial to any surface.
• To avoid contamination, discard remaining contents after use. Do not save solution in an opened vial. Do not re-use. 

- Each unit dose vial is packaged for one-time use only. Reuse of this unit dose device can increase the risk of eye infection.
- If swallowed, get medical help.
- If solution changes color or becomes cloudy, do not use.
- This product contains a level of boric acid that is safe when used according to label instructions. Boric acid has a potential to cause reproductive toxicity.
- Use before the expiration date marked on the product. 
- Store between 15°C to 30°C. 
- Keep out of the reach of children. 

RESIDUAL RISKS AND UNDESIRABLE ADVERSE EFFECTS:
Possible residual risks and/or undesirable side effects for SYSTANE™ ULTRA UD Lubricant Eye Drops include: allergic response/hypersensitivity, decreased vision (temporary and permanent), eye pain, irritation, microbial infection, redness of the eye, systemic toxicity, and toxicity response.

If you experience persistent eye discomfort, eye pain, excessive tearing, vision changes or redness of the eye, stop using SYSTANE™ ULTRA UD Lubricant Eye Drops and consult your eye care professional as the problem could become more serious.

Serious Incident Reporting:
Any serious incident related to the use of this medical device should be reported to Alcon Laboratories, Inc.:

Contact the local country office or your Alcon distributor.
Email: apac.complaint@alcon.com
In Vietnam: apac.complaint@alcon.com
Website: <https://www.alcon.com/contact-us>

These serious incidents should also be reported to the competent authority for medical devices of your country.

HOW SUPPLIED:
SYSTANE™ ULTRA UD Lubricant Eye Drops is supplied in sterile single-use plastic vials containing 0.7 mL. Pack size: Box of 30 vials x 0.7ml or Box of 5 vials x 0.7ml.

STERILE A Sterilized using aseptic processing techniques.

GLOSSARY TABLE FOR SYMBOLS

Symbol	Definitions
	Caution
	Consult instructions for use or consult electronic instructions for use
	Do not use if package or unit dose vial is damaged and consult instructions for use
	Date of manufacture
	Contains hazardous substances
	Single sterile barrier system
	Medical Device

WARRANTY:
Not applicable.

STORAGE CONDITION:
Store between 15°C to 30°C.

LEGAL MANUFACTURER:
 Manufacturer
Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, Texas 76134, USA
Based on EU Master Labeling Content- CLEAR ID: TXT000678, Rev 0525.
ALC-DFU Systane Ultra UD-V0525

Alcon

438492