

SILKTEARS- glycerin ophthalmic solution solution/ drops

SilkTears

Purpose

Lubricant

Dosage and Administration

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

For external use only.

Do not use if solution changes color or becomes cloudy.

When using this product:

- do not touch tip of container to any surface to avoid contamination
- do not reuse
- once opened, discard

Stop use and ask a doctor if you experience:

- eye pain
- changes in vision
- continued redness or irritation

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Inactive ingredients: dextrose, magnesium chloride, purified water, Silk-Derived Protein-4 (SDP-4), sodium acetate. May also contain hydrochloric acid and/or sodium hydroxide to adjust PH

For the temporary relief of burning and irritation due to dryness of the eye.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Glycerin 0.2% - Lubricant

30 vials of 6 pouches each containing 5 sterile dispensers 0.01 FL OZ (0.35 mL EA)

Ingredient Name	Strength
DEXTROSE (UNII: IY9XDZ35W2)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
AMLISIMOD (UNII: K80BPM67OF)	10 mg in 1000 mL
SODIUM ACETATE (UNII: 4550K0SC9B)	
WATER (UNII: 059QF0K00R)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85837-0001-3	30 in 1 BOX	06/25/2025	
1		0.4 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M018	06/25/2025	

Labeler - SilkTears (119521895)

Registrant - SilkTears (119521895)

Establishment

Name	Address	ID/FEI	Business Operations
Unither Manufacturing LLC		079176615	manufacture(85837-0001)

Revised: 7/2025

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