

## **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.

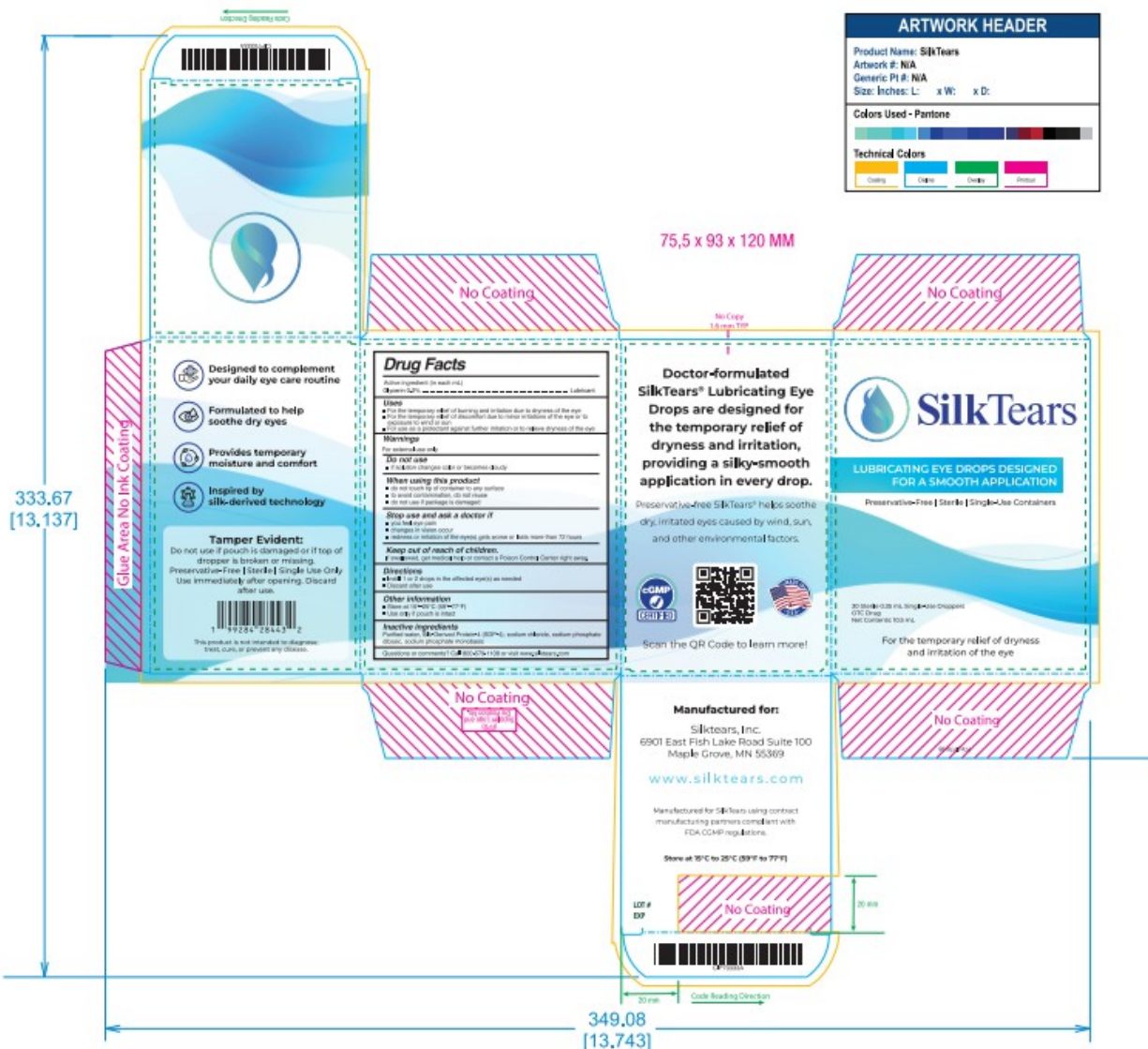
Inactive ingredients: purified water, Silk-Derived Protein-4 (SDP-4), sodium chloride, sodium phosphate dibasic, sodium phosphate monobasic.

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 0.4% – Lubricant

SilkTears 0.4 mL carton (30-count single-use vials)



## SILKTEARS

glycerin ophthalmic solution solution/ drops

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85837-0001
Route of Administration	OPHTHALMIC		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	2 mg in 1000 mL

### Inactive Ingredients

Ingredient Name	Strength
-----------------	----------

<b>SODIUM PHOSPHATE, DIBASIC, ANHYDROUS</b> (UNII: 22ADO53M6F)	
<b>SODIUM PHOSPHATE, MONOBASIC, ANHYDROUS</b> (UNII: KH7I04HPUU)	
<b>AMLISIMOD</b> (UNII: K80BPM67OF)	10 mg in 1000 mL
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>WATER</b> (UNII: 059QF0KO0R)	

### 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: 6/2025

SilkTears