

**SYSFOL EYE DROPS- polyethylene glycol 400, propylene glycol liquid  
Unimed Pharmaceuticals, Inc.**

*Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.*

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**Drug Facts**

Polyethylene Glycol 400, Propylene Glycol

boric acid, hypromellose, potassium chloride, purified water, sodium chloride, sodium hyaluronate, sodium, hydroxide

for use as a protectant against further irritation or to relieve dryness of the eye

keep out of reach of the children

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

For external use only

When using this product

■ do not touch tip of container to any surface to avoid contamination

■ replace cap after each use

■ avoid direct sunlight

external use only

0.33 FL OZ (10mL)

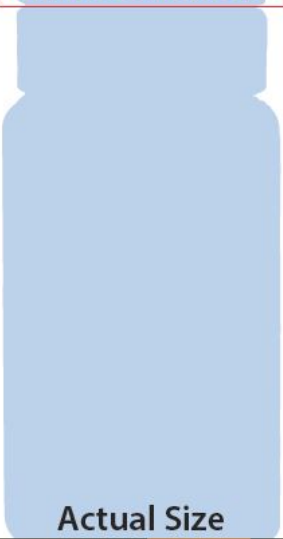
Preservative-free  
Lubricant Eye drops  
**Sysfol Eye Drops**  
Polyethylene Glycol 400 0.4%  
Propylene Glycol 0.3%

Compare to the active ingredients in Systane® Hydration Preservative-Free Eye Drops  
**Preservative-free Lubricant Eye drops**  
**Sysfol Eye Drops**  
Polyethylene Glycol 400 0.4%, Propylene Glycol 0.3%  
0.33 FL OZ (10mL)  
UNIMED PHARM INC.

MANUFACTURED BY:  
UNIMED PHARMACEUTICALS INC.  
132, Osongsaengmyeong6-ro,  
Osong-eup, Heungdeok-gu, Cheonju-si,  
Chungcheongbuk-do, Korea

**KEEP OUTER CARTON FOR  
COMPLETE WARNINGS AND  
PRODUCT INFORMATION.**

**TAMPER EVIDENT: DO NOT  
USE IF NECKBAND ON THE  
BOTTLE IS BROKEN OR MISSING.**



<b>Drug Facts</b>	
<b>Active ingredient</b>	<b>Purpose</b>
Polyethylene Glycol 400 0.4% .....Lubricant	
Propylene Glycol 0.3% .....Lubricant	
<b>Uses</b>	
<ul style="list-style-type: none"> <li>for use as a protectant against further irritation or to relieve dryness of the eye</li> </ul>	
<b>Warnings</b> For external use only	
<b>Do not use</b>	
<ul style="list-style-type: none"> <li>if this product changes color or becomes cloudy</li> <li>if you are sensitive to any ingredient in this product</li> </ul>	
<b>When using this product</b>	
<ul style="list-style-type: none"> <li>do not touch tip of container to any surface to avoid contamination</li> <li>replace cap after each use</li> </ul>	
<b>Stop use and ask a doctor if</b> you experience any of the following:	

<b>Drug Facts(continued)</b>
<ul style="list-style-type: none"> <li>eye pain</li> <li>changes in vision occur</li> <li>continued redness or irritation of the eye</li> <li>condition worsens or persists for more than 72 hours</li> </ul>
<b>Keep out of the reach of children.</b>
If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) immediately.
<b>Directions</b>
Instill 1 or 2 drops in the affected eye(s) as needed
<b>Other information</b>
<ul style="list-style-type: none"> <li>store at temperature, not exceeding 59°F (15 °C)</li> </ul>
<b>Inactive ingredients</b>
boric acid, hypromellose, potassium chloride, purified water, sodium chloride, sodium hyaluronate, sodium hydroxide

<b>SYSFOL EYE DROPS</b>			
polyethylene glycol 400, propylene glycol liquid			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:73669-013
<b>Route of Administration</b>	OPHTHALMIC		
<b>Active Ingredient/Active Moiety</b>			
Ingredient Name	Basis of Strength	Strength	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ) (POLYETHYLENE GLYCOL 400 - UNII:B697894SGQ)	POLYETHYLENE GLYCOL 400	0.4 g in 100 mL	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3) (PROPYLENE GLYCOL - UNII:6DC9Q167V3)	PROPYLENE GLYCOL	0.3 g in 100 mL	

## Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73669-013-02	30 in 1 BOX	04/20/2023	
1	NDC:73669-013-01	0.4 mL in 1 CONTAINER; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		04/20/2023	

**Labeler** - Unimed Pharmaceuticals, Inc. (689852052)

**Registrant** - Unimed Pharmaceuticals, Inc. (689852052)

## Establishment

Name	Address	ID/FEI	Business Operations
Unimed Pharmaceuticals, Inc.		689852052	label(73669-013) , manufacture(73669-013) , pack(73669-013)

Revised: 5/2023

Unimed Pharmaceuticals, Inc.