

**SPLASH PURE PF- propylene glycol solution/ drops**  
**LABORATORIOS SOPHIA, S.A. DE C.V.**

-----  
**Splash**

***Drug Facts***

***Active ingredient***

Propylene Glycol 0.6%

***Purpose***

Eye Lubricant

***Uses***

- for the temporary relief of burning and irritation due to dryness of the eye.
- for use as a protectant against further irritation or to relieve dryness of the eye.

***Warnings***

**For external use only**

**Do not use**

- if this product changes color or becomes cloudy.
- if you are sensitive to any ingredient in this product.

**When using this product**

- do not touch the nozzle tip to any surface.
- replace cap after each use.

**Stop use and ask a doctor if**

- eye pain, changes in vision, continued redness or irritation of the eye.
- condition worsens or persists for more than 72 hours.

**Keep out of reach of children.**

if swallowed, get medical help or contact a Poison Control Center right away.

***Directions***

- shake well before using.
- instill 1 or 2 eye drops in the affected eye(s) as needed.

***Other information***

store at room temperature

***Inactive ingredients***

boric acid, castor oil, dimyristoyl phosphatidylcholine (DMPC), disodium edetate dihydrate, glycerin, hyaluronate sodium, polysorbate 80, sodium borate decahydrate, water for injection.

***Questions?***

Call 1-866-282-8871

splasheyedrops.com

HYDRATES

REPLENISHES

**NDC 57619-307-01**

Distributed by:

**LABS SOPHIA USA, INC**

1790 Hughes Landing Blvd Suite

400, The Woodlands, TX 77380

MADE IN MEXICO

**DIRECTIONS**

- Before first use, squeeze until the first drop is released and discard it.
- After each use, shake the bottle to remove any residual liquid from the nozzle tip.
- Discard 30 days after opening.

**See full instructions inside before use.**

**TAMPER EVIDENT**

Do not use if the tamper evident ring under cap is broken or missing.

SOPHIA ®

ADVANCED HYDRATION

Splash ®

Propylene Glycol 0.6%

Lubricant Eye Drops

PURE PF

Dry Eye Relief

Preservative-Free

0.34 FL OZ (10mL) STERILE



Propylene Glycol 0.6% Lubricant Eye Drops



# Splash

37462

### Drug Facts

Active ingredient	Purpose
Propylene Glycol 0.6%	Eye Lubricant

**Uses**

- for the temporary relief of burning and irritation due to dryness of the eye.
- for use as a protectant against further irritation or to relieve dryness of the eye.

**Warnings**  
For external use only

**Do not use**

- if this product changes color or becomes cloudy.
- if you are sensitive to any ingredient in this product.

**When using this product**

- do not touch the nozzle tip to any surface.
- replace cap after each use.

**Stop use and ask a doctor if you experience any of the following:**

- eye pain, changes in vision, continued redness or irritation of the eye.
- condition worsens or persists for more than 72 hours.

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

**Directions**

- shake well before using.
- instill 1 or 2 eye drops in the affected eye(s) as needed.

**Drug Facts**  
(continued)

**Other information**

- store at room temperature

**Inactive ingredients**

boric acid, castor oil, dimyristoyl phosphatidylcholine (DMPC), disodium edetate dihydrate, glycerin, hyaluronate sodium, polysorbate 80, sodium borate decahydrate, water for injection.

**Questions?**  
Call 1-866-282-8871  
splasheyedrops.com

**DIRECTIONS**

- Before first use, squeeze until the first drop is released and discard it.
- After each use, shake the bottle to remove any residual liquid from the nozzle tip.
- Discard 30 days after opening.

See full instructions inside before use.

**TAMPER EVIDENT**  
Do not use if the tamper evident ring under cap is broken or missing.



ADVANCED HYDRATION

# Splash

Propylene Glycol 0.6%  
Lubricant Eye Drops



## Pure PF

### Dry Eye Relief

Preservative-Free

0.34 FL OZ (10mL)      STERILE



**HYDRATES  
REPLENISHES**




**NDC 57619-307-01**  
Distributed by:  
**LABS SOPHIA USA, INC**  
1790 Hughes Landing Blvd Suite  
400, The Woodlands, TX 77380  
MADE IN MEXICO

## SPLASH PURE PF

propylene glycol solution/ drops

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:57619-307
<b>Route of Administration</b>	OPHTHALMIC		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3) (PROPYLENE GLYCOL - UNII:6DC9Q167V3)	PROPYLENE GLYCOL	6 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>HYALURONATE SODIUM</b> (UNII: YSE9PPT4TH)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>CASTOR OIL</b> (UNII: D5340Y2I9G)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>BORIC ACID</b> (UNII: R57ZHV85D4)	
<b>SODIUM BORATE</b> (UNII: 91MBZ8H3QO)	
<b>DIMYRISTOYLPHOSPHATIDYLCHOLINE, DL-</b> (UNII: U86ZGC74V5)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57619-307-01	1 in 1 CARTON	10/06/2025	
1		10 mL in 1 BOTTLE; 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	10/06/2025	

**Labeler** - LABORATORIOS SOPHIA, S.A. DE C.V. (810143636)

## Establishment

Name	Address	ID/FEI	Business Operations
LABORATORIOS SOPHIA, S.A. DE C.V.		810143636	manufacture(57619-307)

Revised: 10/2025

LABORATORIOS SOPHIA, S.A. DE C.V.