

SPLASH PURE PF- propylene glycol emulsion
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

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MADE IN MEXICO

SPLASH PURE PF

propylene glycol emulsion

Product Information

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

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
WATER (UNII: 059QF0KO0R)	
CASTOR OIL (UNII: D5340Y2I9G)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
BORIC ACID (UNII: R57ZHV85D4)	
SODIUM BORATE (UNII: 91MBZ8H3QO)	
DIMYRISTOYLPHOSPHATIDYLCHOLINE, DL- (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: 11/2025

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