SPLASH TEARS- hypromellose solution/ drops
LABORATORIOS SOPHIA, S.A. DE C.V.

Splash Tears

Drug Facts

Active ingredient

Hypromellose 0.2%

Purpose

Lubricant eye drops

Uses

Temporarily relieves
- burning and irritation due to dryness of the eye.
- discomfort due to minor irritations of the eye or to exposure to wind or sun.

Warnings

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.
- replace cap after using.

Stop use and ask a doctor if
- you experience 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

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

Other information
- store at room temperature
- **do not use** if imprinted seal around cap is broken.

Inactive ingredients

benzalkonium chloride, boric acid, chondroitin sulfate, decahydrate edetate disodium, magnesium chloride hexahydrate, polysorbate 80, potassium chloride, sodium borate, sodium chloride, water for injection

Questions?

Call **1-866-282-8871**

www.splashtears.com

NDC 57619-303-01

Distributed by:

LABS SOPHIA USA, INC.

1790 Hughes Landing Blvd Suite 400

The Woodlands, TX 77380

MADE IN MEXICO

www.splashtears.com

LONG LASTING

Splash TEARS®

Lubricant Eye Drops

Dry Eye Relief

Fast-Acting Hydration

1/2 FL OZ (15 mL)

STERILE

SPLASH TEARS

hypromellose solution/ drops

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:57619-303
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HYPROMELLOSE 2910 (4000 MPA.S) (UNII: RN3152OP35) (HYPROMELLOSE 2910 (4000 MPA.S) - UNII:RN3152OP35)	HYPROMELLOSE 2910 (4000 MPA.S)	0.2 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
CHONDROITIN SULFATE (BOVINE) (UNII: 6IC1M3OG5Z)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
WATER (UNII: 059QF0KO0R)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
SODIUM BORATE (UNII: 91MBZ8H3QO)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
BORIC ACID (UNII: R57ZHV85D4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57619-303-01	1 in 1 CARTON	05/13/2020	
1		15 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		
2	NDC:57619-303-03	1 in 1 CARTON	07/24/2020	
2		2 mL in 1 BOTTLE, DROPPER; 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	05/13/2020	

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(57619-303)

Revised: 1/2024 LABORATORIOS SOPHIA, S.A. DE C.V.