SPLASH REDNESS RELIEVER- hypromellose, naphazoline hydrochloride solution/ drops
LABORATORIOS SOPHIA, S.A. DE C.V.

Splash Redness Reliever

Drug Facts

Active ingredient . . . . . ***Purpose***
Hypromellose 0.2%.....Lubricant
Naphazoline hydrochloride 0.02%.....Redness reliever

Purpose

Uses

Temporarily relieves
- redness due to minor eye irritation
- protection against further irritation
- burning and irritation due to dryness of the eye

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.

ask a doctor before use if you have narrow angle glaucoma.

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.
- overuse may cause more redness of the eye
- pupil may become enlarged temporarily

Keep out of reach of children.

If swallowed, get medical help or contat a Poison Control Center right away

Directions

Instill 1 or 2 drops in the affected eye(s) up to 4 times daily.

Other information

- store at room temperature
- **do not use** if imprinted seal around cap is broken
- remove contact lenses before using

Inactive ingredients

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

Questions?

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

splashtears.com

Sophia ®

REDNESS RELIEVER

Splash ®

Lubricant

Redness Reliever Eye Drops

Red Eye Relief

Fast-Acting Reliever
0.5 FL OZ (15 mL)

STERILE

RELIEVES REDNESS BURNING IRRITATION

NDC 57619-304-01
Distributed by:
LABS SOPHIA USA, INC
1790 Hughes Landing Blvd, Suite 400
The Woodlands, TX 77380
MADE IN MEXICO

splashtears.com

SPLASH REDNESS RELIEVER

hypromellose, naphazoline hydrochloride solution/ drops

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:57619-304

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
NAPHAZOLINE HYDROCHLORIDE (UNII: MZ1131787D) (NAPHAZOLINE - UNII:H231GF11BV)	NAPHAZOLINE HYDROCHLORIDE	0.02 g in 100 mL

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57619-304-01	1 in 1 CARTON	04/25/2023	
1		15 mL in 1 BOTTLE, PLASTIC; 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	04/25/2023	

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(57619-304)