

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

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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 contact 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, decahydrate edetate disodium, magnesium chloride hexahydrate, polysorbate 80, potassium chloride, sodium borate, sodium chloride, water for injection.

Questions?

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

splashtears.com

Splash ®

Redness Reliever

Lubricant redness reliever Eye drops

Fast-Acting Reliever

0.5 FL OZ (15 mL)

Relieves REDNESS BURNING IRRITATION

Sophia ®

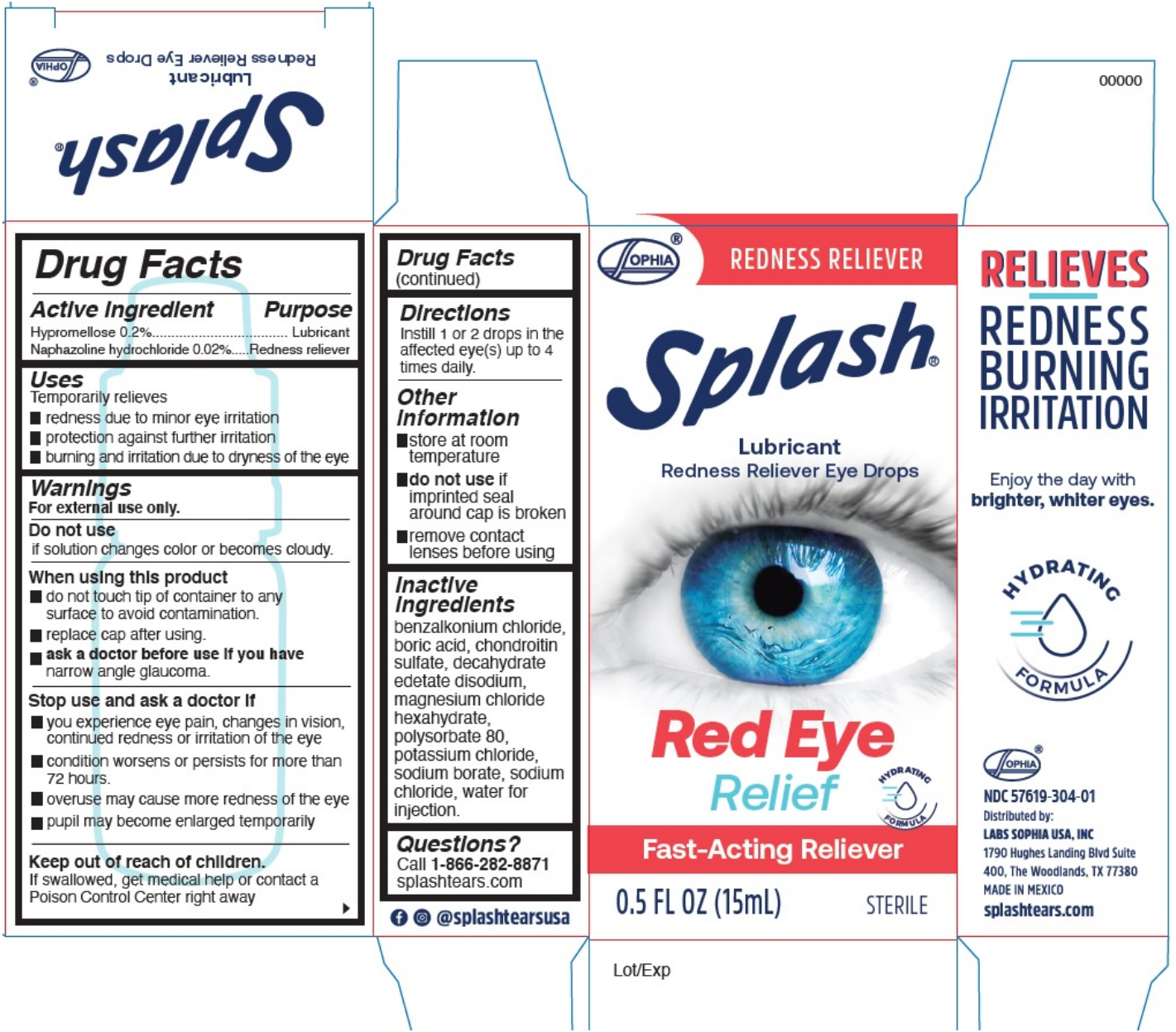
Distributed by:

LABS SOPHIA USA, INC

1790 Hughes Landing Blvd, Suite 400

The Woodlands, TX 77380

MADE IN MEXICO



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
WATER (UNII: 059QF0KO0R)	
SODIUM BORATE (UNII: 91MBZ8H3QO)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
CHONDROITIN SULFATE (BOVINE) (UNII: 6IC1M3OG5Z)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
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 final	part349	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)

Revised: 5/2023

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