

OPTIC SPLASH- naphazoline hydrochloride, glycerin solution/ drops
Sato Pharmaceutical, Co., Ltd.

Optic Splash

Active ingredients

Glycerin 0.2%

Naphazoline hydrochloride 0.02%

Purpose

Glycerin Lubricant

Naphazoline hydrochloride Redness reliever

Uses

- Relieves redness of the eye due to minor eye irritations.
- Temporarily relieves burning and irritation due to dryness of the eye.

Warnings

For external use only

Do not use

- if solution changes color or becomes cloudy

Ask a doctor before use if you have

- narrow angle glaucoma

When using this product

- to avoid contamination, do not touch tip of container to any surface
- replace cap after using
- overuse of this product may produce increased redness of the eye
- pupils may become enlarged temporarily

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 to 2 drops in the affected eye(s) up to four times daily.

Other information

■ store tightly closed, protected from light.

Inactive ingredients

benzalkonium chloride, boric acid, camphor, menthol, polysorbate 80, potassium chloride, purified water, sodium borate, sodium chloride

opticsplashcart.jpg



OPTIC SPLASH

naphazoline hydrochloride, glycerin solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49873-501
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NAPHAZOLINE HYDROCHLORIDE (UNII: MZ1131787D) (NAPHAZOLINE - UNII:H231GF11BV)	NAPHAZOLINE HYDROCHLORIDE	20 mg in 100 mL
GLYCERIN (UNII: PDC6A3C00X) (GLYCERIN - UNII:PDC6A3C00X)	GLYCERIN	200 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
BORIC ACID (UNII: R57ZHV85D4)	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
LEVOMENTHOL (UNII: BZ1R15MTK7)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SODIUM BORATE (UNII: 91MBZ8H3QO)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49873-501-01	1 in 1 CARTON	01/22/2008	
1		15 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	01/22/2008	

Labeler - Sato Pharmaceutical, Co., Ltd. (690575642)**Establishment**

Name	Address	ID/FEI	Business Operations
Sato Pharmaceutical, Co. Ltd.		715699133	manufacture(49873-501) , label(49873-501) , pack(49873-501)

Revised: 12/2023

Sato Pharmaceutical, Co., Ltd.