

**CAREONE MAXIMUM STRENGTH REDNESS RELIEF- glycerin, and naphazoline hydrochloride solution/ drops
FOODHOLD U.S.A., LLC**

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.

CareOne Redness Relief Max 0.5oz (NBE Clear Eyes Max)

Active ingredients Purpose

Glycerin 0.5%..... Eye Lubricant

Naphazoline HCl 0.03%.....Eye Redness reliever

Uses

- for the relief of redness of the eye due to minor eye irritations
- for the temporary relief of burning and irritation due to the dryness of the eye
- for use as a protectant against further irritation or 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

- do not touch tip of container to any surface to avoid contamination
- replace cap after each use
- pupils may become enlarged temporarily
- overuse may cause more eye redness
- remove contact lenses before using

Stop use and ask a doctor if

- you feel eye pain
- changes in vision occur
- redness or irritation of the eye lasts
- condition worsens or lasts more than 72 hours

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

- to open bottle, push cap down and twist counterclockwise
- instill 1 to 2 drops in the affected eye(s) up to 4 times daily
- children under 6 years of age: ask a doctor

Other information

- store at room temperature 20-25°C (68-77°F)

Inactive ingredients

benzalkonium chloride, boric acid, edetate disodium, purified water, sodium borate

Distributed by:

FOODHOLD U.S.A., LLC

LANDOVER, MD 20785

Made in South Korea



CAREONE MAXIMUM STRENGTH REDNESS RELIEF

glycerin, and naphazoline hydrochloride solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-790
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GLYCERIN (UNII: PDC6A3C00X) (GLYCERIN - UNII:PDC6A3C00X)	GLYCERIN	0.0025 mg in 1 mL
NAPHAZOLINE HYDROCHLORIDE (UNII: MZ1131787D) (NAPHAZOLINE - UNII:H231GF11BV)	NAPHAZOLINE HYDROCHLORIDE	0.00015 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
BORIC ACID (UNII: R57ZHV85D4)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
WATER (UNII: 059QF0KO0R)	
SODIUM BORATE (UNII: 91MBZ8H3QO)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-790-15	1 in 1 BOX	05/18/2017	
1		15 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 final	part349	05/18/2017	

Labeler - FOODHOLD U.S.A., LLC (809183973)