

**CAREONE EYE DROPS SEASONAL RELIEF- tetrahydrozoline hcl and zinc sulfate 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 Eye Drops Seasonal Relief 0.5 oz (NBE Visine AC) 86533 2018

Active Ingredients Purposes

Tetrahydrozoline HCl 0.05%.....Eye redness reliever

Zinc sulfate 0.25%.....Eye astringent

Uses

- for temporary relief of discomfort and redness of the eye due to minor eye irritations

For external use only

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

When using this product

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

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
- put 1 to 2 drops in the affected eye(s) up to 4 times daily
- children under 6 years of age: ask a doctor

- some users may experience a brief tingling sensation
- store between 15-25°C (59-77°F)

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

Questions or comments?

Call 1-877-846-9949

Distributed by:

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CAREONE EYE DROPS SEASONAL RELIEF

tetrahydrozoline hcl and zinc sulfate solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-653
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TETRAHYDROZOLINE HYDROCHLORIDE (UNII: 0 YZT43HS7D) (TETRAHYDROZOLINE - UNII:S9U025Y077)	TETRAHYDROZOLINE HYDROCHLORIDE	0.5 mg in 1 mL
ZINC SULFATE (UNII: 89DS0H96TB) (ZINC CATION - UNII:13S1S8SF37)	ZINC SULFATE	2.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
EDETATE DISODIUM (UNII: 7FLD91C86K)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
BORIC ACID (UNII: R57ZHV85D4)	
WATER (UNII: 059QF0K00R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-653-15	1 in 1 BOX	10/01/2018	
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 final	part349	09/26/2018	

Labeler - FoodHold U.S.A LLC (809183973)

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FoodHold U.S.A LLC