IRRITATION RELIEF EYE- tetrahydrozoline hydrochloride and zinc sulfate solution/ drops WinCo Foods, 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.

Active ingredients

Tetrahydrozoline HCl 0.05%

Zinc sulfate 0.25%

Purpose

Tetrahydrozoline HCl...Redness Reliever

Zinc sulfate...Astringent

Uses

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

Warnings

For external use only

Ask a doctor before use if you have narrow angle glaucoma

When using this product

- pupils may become enlarged temporarily
- to avoid contamination, do not touch tip of container to any surface. Replace cap after using.
- if solution changes color or becomes cloudy, do not use
- overuse may produce increased redness of the eye
- remove contact lens before using

Stop use and ask a doctor if you experience

- eye pain
- changes in vision
- continued redness or irritation of the eye, or if the condition worsens or persists for 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 right away.

Directions

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

Other information

Store at 15°-30°C (59°-86°F)

Inactive ingredients

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

Eve Drops IRRITATION RELIEF

Winco

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Compare to the active ingredients in VISINE A.C.*



Relieves Irritation & Red Eyes

Seasonal Relief



RETAIN THIS CARTON FOR FUTURE REFERENCE

TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF IMPRINTED NECKBAND IS MISSING OR BROKEN.

DISTRIBUTED BY: WINCO FOODS, LLC, BOISE, ID 83704

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*This product is not manufactured or distributed by JOHNSON & JOHNSON, HEALTHCARE PRODUCTS, distributor of VISINE® A.C.®

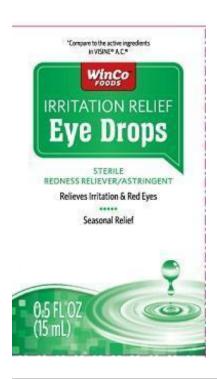
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Comments & Questions? 800-824-1706 www.wincofoods.com

CEDACO05/WCD





IRRITATION RELIEF EYE

tetrahydrozoline hcl, zinc sulfate solution/ drops

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67091-283
Route of Administration	OPHTHALMIC	DEA Sche dule	

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
TETRAHYDRO ZOLINE HYDRO CHLO RIDE (UNII: 0 YZT43HS7D) (TETRAHYDRO ZOLINE - UNII:S9 U0 25 Y0 77)	TETRAHYDROZOLINE HYDROCHLORIDE	50 mg in 100 mL	
ZINC SULFATE (UNII: 89 DS0 H96 TB) (ZINC CATION - UNII:13S1S8 SF37)	ZINC CATION	250 mg in 100 mL	

Inactive Ingredients			
Ingredient Name	Strength		
BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7)			
BORIC ACID (UNII: R57ZHV85D4)			
EDETATE DISO DIUM (UNII: 7FLD91C86K)			
WATER (UNII: 059QF0KO0R)			
SODIUM CHLORIDE (UNII: 451W47IQ8X)			
SODIUM CITRATE (UNII: 1Q73Q2JULR)			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67091-283-15	1 in 1 BOX		
1		15 mL in 1 BOTTLE, DROPPER		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part349	01/09/2015		

Labeler - WinCo Foods, LLC (056098817)

Registrant - KC Pharmaceuticals, Inc. (174450460)

Establishment			
Name	Address	ID/FEI	Business Operations
KC Pharmaceuticals, Inc.		174450460	manufacture(67091-283), label(67091-283), pack(67091-283)

Revised: 2/2015 WinCo Foods, LLC