

**WINCO ORIGINAL FORMULA EYE DROPS- tetrahydrozoline hcl liquid**  
**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.*

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**Drug Facts**

***Active ingredient***

Tetrahydrozoline HCL 0.05%

***Purpose***

Redness reliever

***Uses***

- relieves 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 (1-800-222-1222) right away.

***Directions***

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

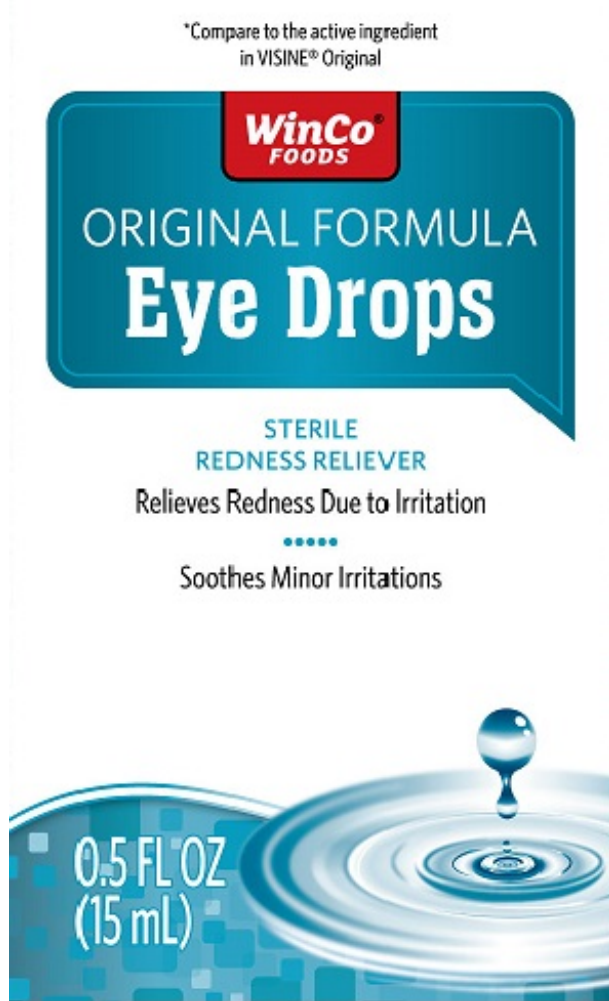
**Other information**

store at 15-30°C (59°-86°F)

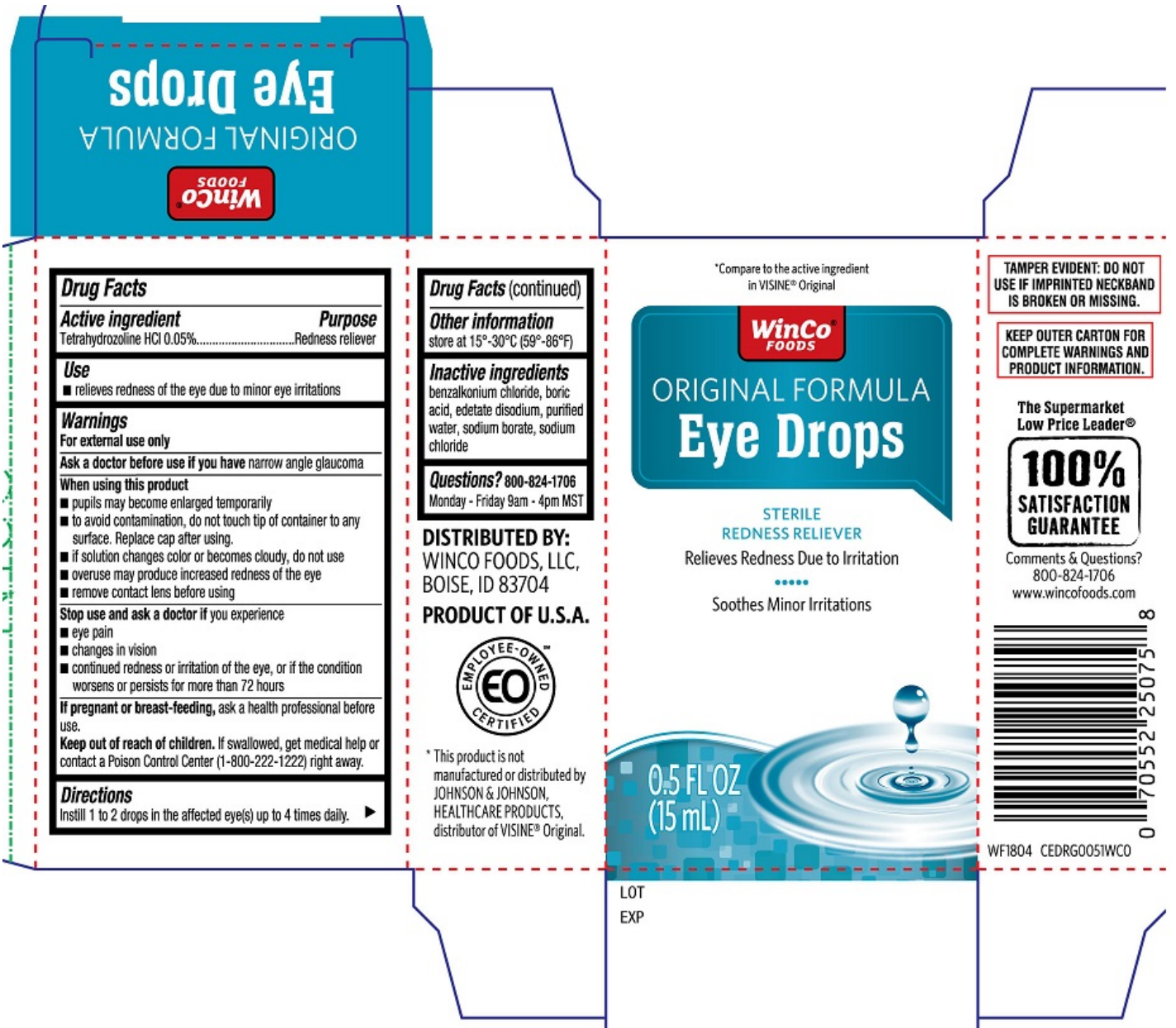
**Inactive ingredients**

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

**PDP**



**Carton**



## WINCO ORIGINAL FORMULA EYE DROPS

tetrahydrozoline hcl liquid

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67091-310
Route of Administration	OPHTHALMIC		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TETRAHYDROZOLINE HYDROCHLORIDE (UNII: 0 YZT43HS7D) (TETRAHYDROZOLINE - UNII:S9U025Y077)	TETRAHYDROZOLINE HYDROCHLORIDE	0.05 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7)	
<b>BORIC ACID</b> (UNII: R57ZHV85D4)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BORATE</b> (UNII: 91MBZ8H3QO)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67091-310-15	1 in 1 CARTON	09/26/2018	
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	09/26/2018	

**Labeler** - WinCo Foods, LLC (056098817)

**Registrant** - KC Pharmaceuticals, Inc. (174450460)

### Establishment

Name	Address	ID/FEI	Business Operations
KC Pharmaceuticals, Inc.		174450460	manufacture(67091-310) , pack(67091-310) , label(67091-310)

Revised: 9/2018

WinCo Foods, LLC