CAREONE ITCHY RELIEF EYE DROPS 15ML- tetrahydrozoline hci, zinc sulfate liquid
Retail Business Services, 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 HCI 0.05%

Zinc sulfate 0.25%

Purposes

Redness reliever

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 lenses 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 to 2 drops in the affected eye(s) up to 4 times daily

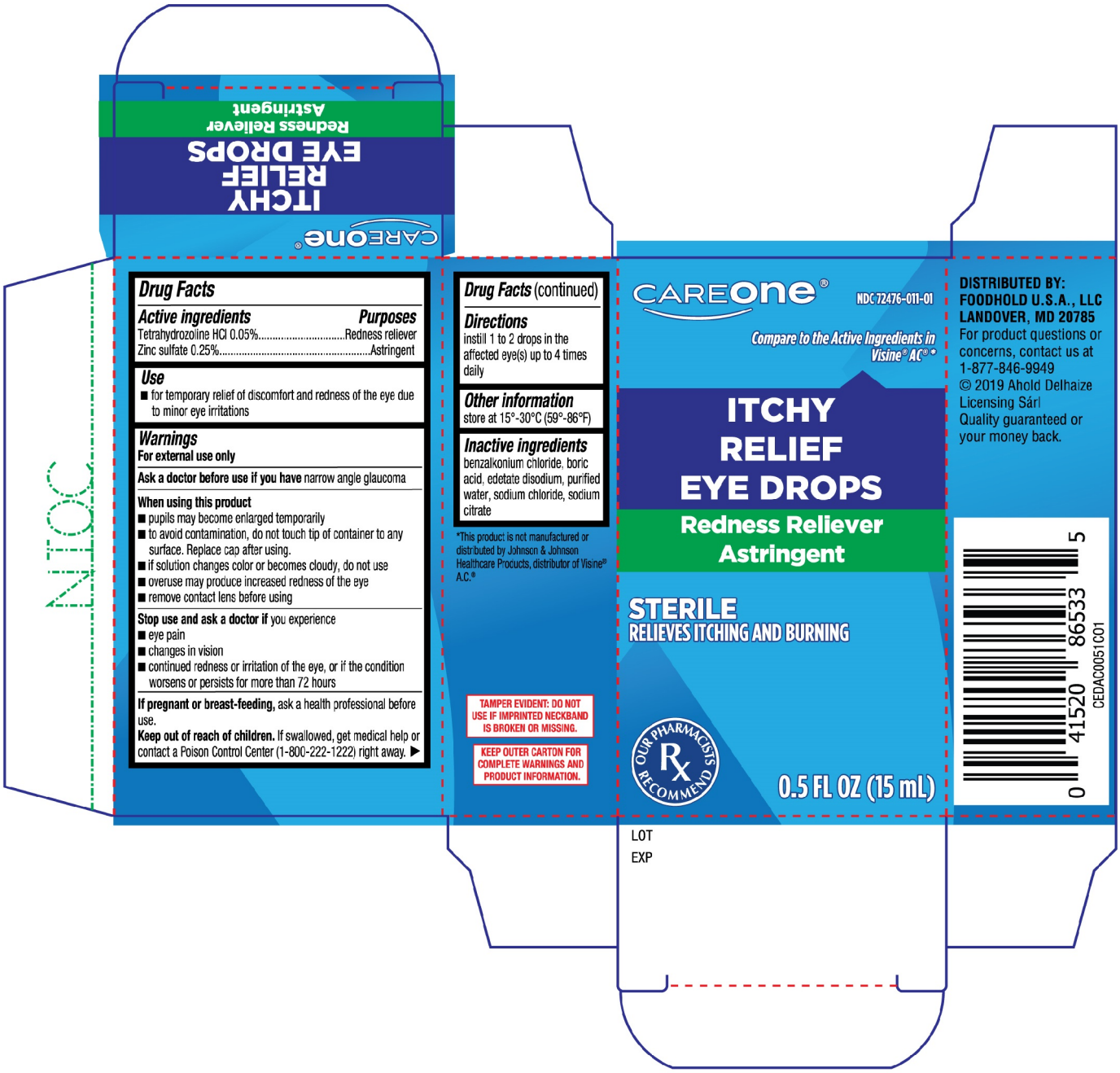
Other information

store at 15°-30°C (59°-86°F)

Inactive ingredients

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

Careone Itchy Relief Eye Drops 15mL



CAREONE ITCHY RELIEF EYE DROPS 15ML

tetrahydrozoline hci, zinc sulfate liquid

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:72476-011
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ZINC SULFATE (UNII: 89DS0H96TB) (ZINC CATION - UNII:13S1S8SF37)	ZINC SULFATE	0.25 g in 100 mL
TETRAHYDROZOLINE HYDROCHLORIDE (UNII: 0YZT43HS7D) (TETRAHYDROZOLINE - UNII:S9U025Y077)	TETRAHYDROZOLINE HYDROCHLORIDE	0.05 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
BORIC ACID (UNII: R57ZHV85D4)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:72476-011-01	1 in 1 BOX	10/29/2019	
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	10/29/2019	

Labeler - Retail Business Services, LLC. (967989935)

Registrant - KC Pharmaceuticals, Inc. (174450460)

Establishment

Name	Address	ID/FEI	Business Operations
KC Pharmaceuticals, Inc.		174450460	manufacture(72476-011) , pack(72476-011) , label(72476-011)

Revised: 12/2019 Retail Business Services, LLC.