

QUALITY CHOICE ORIGINAL EYE DROPS- tetrahydrozoline hydrochloride solution
CHAIN DRUG MARKETING ASSOCIATION INC

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 ingredient

Purpose

Tetrahydrozoline HCL 0.05%.....Redness reliever

Uses

- for the relief of redness of the eyes due to minor eye irritations

Warnings

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
- to avoid contamination, do not touch tip of container to any surface
- 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 right away.

Directions

- To open bottle, push cap down and twist counterclockwise. To close bottle, twist clockwise until it stops turning
- put 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

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

Inactive ingredients: benzalkonium chloride, boric acid, edetate disodium, purified water, sodium chloride, and sodium borate

Distributed by

C.D.M.A., Inc.

43157 W. Nine Mile

Novi, MI 48376-0995



QUALITY CHOICE ORIGINAL EYE DROPS

tetrahydrozoline hydrochloride solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-903
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

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-903-15	1 in 1 CARTON	03/22/2017	
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	09/30/2012	

Labeler - CHAIN DRUG MARKETING ASSOCIATION INC (011920774)

Revised: 3/2017

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