

SOUND BODY ORIGINAL EYE- tetrahydrozoline hydrochloride solution/ drops
United Exchange Corp

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.

Drug Facts

Active ingredient

Tetrahydrozoline HCl 0.05%

Purpose

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
- 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 last more than 72 hours

If pregnant or breast-feeding,

ask a health professional before use

Keep out of the reach of children.

if swallowed, get medical help or contact a Poison Control Center right away.

Directions

- 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 borate, and sodium chloride

Distributed By:

United Exchange Corp.

17211 Valley View Ave.

Cerritos, CA 90703

Made in Korea



SOUND BODY ORIGINAL EYE

tetrahydrozoline hydrochloride solution/ drops

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:65923-559

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 10 mg

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65923-559-15	1 in 1 CARTON		
1		15 mg in 1 BOTTLE, DROPPER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part349	05/19/2014	

Labeler - United Exchange Corp (840130579)

Revised: 5/2014

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