GOODSENSE ORIGINAL FORMULA EYE- tetrahydrozoline hci solution/ drops Geiss, Destin & Dunn, 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 HCI 0.05%.....Redness reliever

Use

• for the relief of 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
- 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 eve 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

- Ito 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

• store at 15° to 25°C (59° to 77°F)

Inactive ingredients

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

Distributed By:

Geiss, Destin & Dunn, Inc.

Peachtree City, GA 30269

Made in Korea



GOODSENSE ORIGINAL FORMULA EYE

tetrahydrozoline hci solution/ drops

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:50804-015

Route of Administration	OPHTHALMIC
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Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
TETRAHYDRO ZO LINE HYDRO CHLO RIDE (UNII: 0 YZT43HS7D)	TETRAHYDROZOLINE	.5 mg		
(TETRAHYDROZOLINE - UNII:S9U025Y077)	HYDROCHLORIDE	in 1 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 BORATE (UNII: 91MBZ8H3QO)			
SODIUM CHLORIDE (UNII: 451W47IQ8X)			

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:50804-015-05	1 in 1 BOX	03/28/2016		
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	03/28/2016		

Labeler - Geiss, Destin & Dunn, Inc. (076059836)

Revised: 3/2016 Geiss, Destin & Dunn, Inc.