TOPCARE HEALTH ORIGINAL EYE DROPS- tetrahydrozoline hcl solution
Topco Associates 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.

Topcare Original/PLD

Acive ingredient

Tetrahydrozoline HCl.....0.05%

Purpose

Tetrahydrozoline HCl.....Redness reliever

Use

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

Other information

store at 15º-30ºC (59º-86ºF)

Inactive ingredients

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

TOPCARE HEALTH ORIGINAL EYE DROPS

tetrahydrozoline hcl solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:36800-858
Route of Administration	OPHTHALMIC		

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

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:36800-858-01	1 in 1 CARTON	02/06/2020	
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	02/06/2020	

Labeler - Topco Associates LLC (006935977)

Registrant - K.C. Pharmaceuticals, Inc (174450460)

Establishment

Name	Address	ID/FEI	Business Operations
K.C. Pharmaceuticals, Inc.		174450460	manufacture(36800-858) , pack(36800-858) , label(36800-858)

Revised: 2/2020 Topco Associates LLC