OPTICAL ORIGINAL EYE DROPS - tetrahydrozoline hydrochloride solution TELEVISA CONSUMER PRODUCTS USA

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

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
- 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

- 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

Televisa Consumer Products USA, LLC

4550 Post Oak Place Suite 326

Houston, TX 77027

Made in Korea



OPTICAL ORIGINAL EYE DROPS tetrahydrozoline hydrochloride solution								
Product Information								
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55038-023					
Route of Administration	OPHTHALMIC							
Active Ingredient/Active Moiety								

Ingredient Name			Basis	ength	Strength		
TETRAHYDRO ZOLINE HYDRO CHLORIDE (UNII: 0 YZT43HS7D) (TETRAHYDROZOLINE - UNII:S9U025Y077)			D)	TETRAHYDROZOLINE HYDROCHLORIDE			0.5 mg in 1 mL
Inactive In	gredients						
Ingredient Name						Strength	
BENZALKON	IUM CHLOF	RIDE (UNII: F5UM2KM3W7)					
BORIC ACID (UNII: R57ZHV85D4)							
EDETATE DISODIUM (UNII: 7FLD91C86K)							
SODIUM CHLORIDE (UNII: 451W47IQ8X)							
SODIUM BOI	RATE (UNII: 9	1MBZ8H3QO)					
WATER (UNI	:059QF0KO	0 R)					
Packaging							
00	1 Code	Package Description	Marketing Start Date		Marketing End Date		
1 NDC:55038	-023-15	1 in 1 CARTON					
1		15 mL in 1 BOTTLE					
Marketii	ng Inform	nation					
Marketing (-	Application Number or Monograph Citation		Marketing Start Date		Marketing End Date	
			-				
OTC monogra	ph final p	art349		10/31/2012			

Labeler - TELEVISA CONSUMER PRODUCTS USA (840246230)

Revised: 10/2012

TELEVISA CONSUMER PRODUCTS USA