LEADER ORIGINAL EYE DROPS- tetrahydrozoline hcl solution/ drops Cardinal Health

Leader Original Eye Drops 15mL (PLD)

Active ingredient

Tetrahydrozoline HCL 0.05%

Purpose

Redness reliever

Uses

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 chlidren

If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222)

right away.

Directions

Instill 1 or 2 drops in the affected eye(s) up to four times daily

Other information

store at 15-30°C (59°-86°F)

Inactive ingredients

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

Questions or comments?

1-888-527-4276

Leader Original Eye Drops 15mL



LEADER ORIGINAL EYE DROPS

tetrahydrozoline hcl solution/ drops

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:70000-0454

Route of Administration OPHTHALMIC

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TETRALYDROZOLINE HYDROCHI ORIDE (LINII) OVZTABLICZD)	TETRALIVEDOZ OLINE	0.05.0

TETRAHYDROZOLINE HYDROCHLORIDE (UNII: 0YZT43HS7D) (TETRAHYDROZOLINE - UNII:S9U025Y077)

TETRAHYDROZ OLINE 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)		

l	Packaging				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
	NDC:70000- 0454-1	1 in 1 CARTON	02/19/2019		
	L	15 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M018	02/19/2019		

Labeler - Cardinal Health (063997360)

Registrant - KC Pharmaceuticals, Inc. (174450460)

Establishment			
Name	Address	ID/FEI	Business Operations
KC Pharmaceuticals, Inc.		174450460	manufacture(70000-0454), pack(70000-0454), label(70000-0454)

Revised: 12/2023 Cardinal Health