

**RUGBY TETRAHYDROZOLINE OPHTHALMIC SOLUTION- tetrahydrozoline
hcl solution/ drops
Rugby Laboratories**

Rugby Tetrahydrozoline Ophthalmic Solution (PLD)

Active Ingredient

Tetrahydrozoline HCl 0.05%

Purpose

Redness Reliever

Use

relieves redness in eye due to minor eye irritations

Warnings

For external use only

Warnings

Ask a doctor before use if you have narrow angle glaucoma

Warnings

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

Warnings

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

Warnings

If pregnant or breast-feeding, ask a professional before use.

Warnings

Keep out of reach of children. If swallowed, get medical help or contact 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 15°-30°C (59°-86°F)

Inactive ingredients

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

Questions or Comments?

1-800-645-2158

Rugby Tetrahydrozoline Ophthalmic Solution



RUGBY TETRAHYDROZOLINE OPHTHALMIC SOLUTION

tetrahydrozoline hcl solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-1217
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
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
BORIC ACID (UNII: R5ZH85D4)	
WATER (UNII: 059QF0K00R)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
EDETATE SODIUM (UNII: MP1J8420LU)	
SODIUM BORATE (UNII: 91MBZ8H3QO)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-1217-94	1 in 1 BOX	06/08/2019	
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 Drug	M018	06/08/2019	

Labeler - Rugby Laboratories (079246066)

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

Establishment

Name	Address	ID/FEI	Business Operations
K.C. Pharmaceuticals, Inc.		174450460	manufacture(0536-1217) , pack(0536-1217) , label(0536-1217)

Revised: 12/2023

Rugby Laboratories