

REDNESS RELIEVER - tetrahydrozoline hcl liquid
Samchundang Pharm. Co., Ltd.

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

Tetrahydrozoline HCl 0.5%

Purpose

Redness reliever

Use

- for the relief of redness of the eye 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 become 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 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

- store between 15° to 25°C (59°F to 77°F)

Inactive ingredients

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

package label

Redness relief

- Fast Redness Relief Formula
- Redness & Irritation Relief

Drug Facts

Active ingredient Purpose
 Tetrahydrozoline HClRedness
 0.05% reliever

Use ■ for relief of redness of the eye due to minor eye irritations

Warnings
 Ask a doctor before use if you have narrow angle glaucoma

When using this product

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- you feel eye pain
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- redness or irritation of the eyes lasts
- condition worsens or lasts more than 72 hours

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

Drug Facts (continued)

Keep out 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
 Store at 15-30°C(59-86°F)

Inactive ingredients
 benzalkonium chloride, boric acid, edetate disodium, hydrochloric acid, purified water, sodium borate, and sodium chloride

Made in Korea



Pure-Aid™
Eye Drop
ORIGINAL
 TETRAHYDROZOLINE HCl
 REDNESS RELIEVER EYE DROPS

Caution: Do not use if the temper-resistant bottle cap is broken or opened.

Pure-Aid™
 •Sterile•
Eye Drop
ORIGINAL
 TETRAHYDROZOLINE HCl
 REDNESS RELIEVER EYE DROPS

Compare to **Visine® ORIGINAL** Eye Drops *

1/2FL.OZ.(15ml)

Pure-Aid™
 •Sterile•
Eye Drop
ORIGINAL
 TETRAHYDROZOLINE HCl
 REDNESS RELIEVER EYE DROPS

Exclusively distributed by:



Kareway Product Inc.
 Compton, CA 90200

*This product is not manufactured or distributed by Pfizer, the distributor of Visine.®

Pure-Aid™
Eye Drop
ORIGINAL
 TETRAHYDROZOLINE HCl
 REDNESS RELIEVER EYE DROPS

LOT

EXP

REDNESS RELIEVER

tetrahydrozoline hcl liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51134-0062
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TETRAHYDROZOLINE HYDROCHLORIDE (UNII: 0 YZT43HS7D) (TETRAHYDROZOLINE - UNII:S9U025Y077)	TETRAHYDROZOLINE HYDROCHLORIDE	0.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BORIC ACID (UNII: R57ZHV85D4)	
SODIUM BORATE (UNII: 91MBZ8H3QO)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WATER (UNII: 059QF0K00R)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51134-0062-5	1 in 1 BOX		
1		15 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part349	08/29/2010	

Labeler - Samchundang Pharm. Co., Ltd. (687792325)

Registrant - Samchundang Pharm. Co., Ltd. (687792325)

Establishment

Name	Address	ID/FEI	Business Operations
Samchundang Pharm. Co., Ltd.		687792325	manufacture

Revised: 8/2010

Samchundang Pharm. Co., Ltd.