

CLEAR EYES COOLING ITCHY EYE RELIEF- naphazoline hydrochloride and glycerin and zinc sulfate liquid

Prestige Brands Holdings, Inc.

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.

Clear Eyes Cooling Itchy Eye Relief

Drug Facts

Active ingredients

Glycerin 0.25%

Purpose

Lubricant

Active ingredients

Naphazoline hydrochloride 0.012%

Purpose

Redness Reliever

Active ingredients

Zinc sulfate 0.25%

Purpose

Astringent

Uses

- For use as a protectant against further irritation or to relieve dryness of the eye.
- For the temporary relief of burning & irritation due to the dryness of the eye.
- Relieves redness of the eye due to minor eye irritations.

Warnings

For external use only.

Do not use

if solution changes color or becomes cloudy.

Ask a doctor before use if

you have narrow angle glaucoma.

When using this product:

- To avoid contamination, do not touch tip of container to any surface.
- Replace cap after using.
- Overuse may produce increased redness of the eye.
- Pupils may become enlarged temporarily.

Stop use & ask a doctor if:

- you experience eye pain
- you experience changes in vision
- you experience continued redness or irritation of the eye
- the condition worsens or persists for more than 72 hours.

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 four times daily.

Other information

- Store at room temperature.
- Remove contact lenses before using.
- **Tamper Evident:** Do not use if neckband on bottle is broken or missing.

Inactive ingredients

benzalkonium chloride, boric acid, cyclodextrin, edetate disodium, menthol, purified water, sodium chloride, sodium citrate

Questions?

1-877-274-1787 www.cleareyes.com

PRINCIPAL DISPLAY PANEL

NEW Clear eyes®
COOLING COMFORT
Astringent/Lubricant/Redness Relief Eye Drops
ITCHY EYE RELIEF
Cools Eye Irritations
Relieves Itching & Burning
STERILE 0.5 FL OZ (15 ML)

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Glycerin 0.25%.....	Lubricant
Naphazoline hydrochloride 0.012%.....	Redness Reliever
Zinc sulfate 0.25%.....	Astringent

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Cools Eyes Instantly!

8 UP TO 8 HOURS OF SOOTHING COMFORT

NEW Clear eyes®

COOLING COMFORT

Astringent / Lubricant / Redness Reliever Eye Drops

ITCHY EYE RELIEF

Soothes and Moisturizes

Revives and Refreshes

COOLING COMFORT

Astringent / Lubricant / Redness Reliever Eye Drops

ITCHY EYE RELIEF

Cools Eye Irritations

Relieves Itching & Burning

STERILE 0.5 FL OZ (15 ML)

Clear eyes®

COOLING COMFORT

Astringent / Lubricant / Redness Reliever Eye Drops

ITCHY EYE RELIEF

Goes beyond ordinary eye drops to renew, refresh, and revitalize eyes. With Occuthol™ an ophthalmic eye cooling solution found only in Clear Eyes® Cooling Comfort.

A Sterile Buffered Solution

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Made in South Africa
CE075103

CLEAR EYES COOLING ITCHY EYE RELIEF

naphazoline hydrochloride and glycerin and zinc sulfate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67172-292
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NAPHAZOLINE HYDROCHLORIDE (UNII: MZ1131787D) (NAPHAZOLINE - UNII:H231GF11BV)	NAPHAZOLINE HYDROCHLORIDE	.12 mg in 1 mL
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	2.5 mg in 1 mL
ZINC SULFATE (UNII: 89DS0H96TB) (ZINC CATION - UNII:13S1S8SF37)	ZINC SULFATE	2.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
BORIC ACID (UNII: R57ZHV85D4)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

MENTHOL (UNII: L7T10EIP3A)	
WATER (UNII: 059QF0KO0R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
BETADEX (UNII: JV039JZZ3A)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67172-292-01	1 in 1 BOX	02/15/2011	
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	02/15/2011	

Labeler - Prestige Brands Holdings, Inc. (159655021)

Establishment

Name	Address	ID/FEI	Business Operations
Aspen SVP Pty Ltd		569162139	MANUFACTURE(67172-292)