

**VISINE RED EYE HYDRATING COMFORT EYE DROPS- tetrahydrozoline hydrochloride and polyethylene glycol 400 solution/ drops
Johnson & Johnson Consumer 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.

VISINE® Red Eye Hydrating Comfort

Drug Facts

Active ingredients	Purpose
Polyethylene glycol 400 1%	Lubricant
Tetrahydrozoline HCl 0.05%	Redness reliever

Uses

- for the relief of redness of the eye due to minor eye irritations
- for the temporary relief of burning, irritation, and discomfort due to dryness of the eye or exposure to wind or sun
- for use as a protectant against further irritation or to relieve dryness of the eye

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
- overuse may cause more eye redness
- remove contact lenses before using
- do not use if this solution changes color or becomes 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

- adults and children 6 years of age and over: put 1 or 2 drops in the affected eye(s) up to 4 times a day
- children under 6 years of age: consult a doctor

- children under 2 years of age: do not use

Other information

Store at 20° to 25°C (68° to 77°F)

Inactive ingredients

ascorbic acid, boric acid, dextrose, glycerin, glycine, hypromellose, magnesium chloride, polyquaternium-42, potassium chloride, purified water, sodium citrate, sodium lactate, sodium phosphate dibasic

Questions?

call toll-free **888-734-7648** or **215-273-8755** (collect)

Distributed by: **JOHNSON & JOHNSON CONSUMER INC.** Skillman, NJ 08558

PRINCIPAL DISPLAY PANEL - 15 mL Bottle Carton

VISINE®

RED EYE

HYDRATING

COMFORT

LUBRICANT/REDNESS RELIEVER EYE DROPS

WORKS IN 30 SECONDS

Redness + Irritation Relief

Lubricates +

Refreshes

STERILE

1/2 FL OZ (15mL)



VISINE RED EYE HYDRATING COMFORT EYE DROPS

tetrahydrozoline hydrochloride and polyethylene glycol 400 solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69968-0356
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
Polyethylene Glycol 400 (UNII: B697894SGQ) (Polyethylene Glycol 400 -	Polyethylene Glycol 400	10 mg

UNII:B697894SGQ)

Polyethylene Glycol 400

in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Ascorbic Acid (UNII: PQ6CK8PD0R)	
Boric Acid (UNII: R57ZHV85D4)	
DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2)	
Glycerin (UNII: PDC6A3C0OX)	
Glycine (UNII: TE7660XO1C)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
Magnesium Chloride (UNII: 02F3473H9O)	
POLIXETONIUM CHLORIDE (UNII: RNW5AM67C0)	
Potassium Chloride (UNII: 660YQ98I10)	
WATER (UNII: 059QF0KO0R)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
Sodium Lactate (UNII: TU7HW0W0QT)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69968-0356-2	1 in 1 CARTON	04/27/2020	
1		15 mL in 1 BOTTLE, DROPPER; Type 4: Device Coated/Impregnated/Otherwise Combined with Drug		
2	NDC:69968-0356-1	700 in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK	04/27/2020	
2		8 mL in 1 BOTTLE, DROPPER; Type 4: Device Coated/Impregnated/Otherwise Combined with Drug		
3	NDC:69968-0356-3	1 in 1 CARTON	04/27/2020	
3		8 mL in 1 BOTTLE, DROPPER; Type 4: Device Coated/Impregnated/Otherwise Combined with Drug		
4	NDC:69968-0356-4	1 in 1 BLISTER PACK	04/27/2020	
4		8 mL in 1 BOTTLE, DROPPER; Type 4: Device Coated/Impregnated/Otherwise Combined with Drug		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part349	04/27/2020	

Labeler - Johnson & Johnson Consumer Inc. (002347102)