

VISINE DRY EYE RELIEF- 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® Dry Eye Relief

Drug Facts

Active ingredient

Polyethylene glycol 400 1%

Purpose

Lubricant

Uses

- for the temporary relief of burning and irritation due to dryness of the eye
- for protection against further irritation

Warnings

For external use only

When using this product

- 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) as needed
- children under 6 years of age: consult a doctor

Other information

Store at room temperature

Inactive ingredients

ascorbic acid, benzalkonium chloride, boric acid, dextrose, disodium phosphate, glycerin, glycine, hypromellose, magnesium chloride, potassium chloride, purified water, sodium borate, sodium chloride, sodium citrate, sodium lactate

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®****DRY EYE RELIEF**

LUBRICANT EYE DROPS

MOISTURIZES +

SOOTHES DRY, GRITTY

EYES

Designed to work

Like Real

Tears

STERILE

1/2 FL OZ (15 mL)



VISINE DRY EYE RELIEF

polyethylene glycol 400 solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69968-0363
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Polyethylene Glycol 400 (UNII: B697894SGQ) (Polyethylene Glycol 400 - UNII:B697894SGQ)	Polyethylene Glycol 400	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Ascorbic Acid (UNII: PQ6CK8PD0R)	
Benzalkonium Chloride (UNII: F5UM2KM3W7)	
Boric Acid (UNII: R57ZHV85D4)	
Dextrose, Unspecified Form (UNII: IY9XDZ35W2)	
Sodium Phosphate, Dibasic, Anhydrous (UNII: 22ADO53M6F)	
Glycerin (UNII: PDC6A3C0OX)	
Glycine (UNII: TE7660XO1C)	
Hypromellose, Unspecified (UNII: 3NXW29V3WO)	
Magnesium Chloride (UNII: 02F3473H9O)	
Potassium Chloride (UNII: 660YQ98I10)	
Water (UNII: 059QF0KO0R)	
Sodium Borate (UNII: 91MBZ8H3QO)	
Sodium Chloride (UNII: 451W47IQ8X)	
Sodium Citrate, Unspecified Form (UNII: 1Q73Q2JULR)	
Sodium Lactate (UNII: TU7HW0W0QT)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69968-0363-1	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:69968-0363-2	2 in 1 CARTON	04/27/2020	
2		15 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)

Revised: 2/2020

Johnson & Johnson Consumer Inc.