# VISINE DRY EYE RELIEF EYE DROPS- 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.

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#### VISINE<sub>®</sub> Dry Eye Relief Tired Eye

Drug Facts

#### **Active ingredient**

Polyethylene glycol 400 1%

#### Purpose

Lubricant

#### Uses

- for the temporary relief of burning, irritation, and discomfort due to dryness of the eye or exposure to wind or sun
- 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, boric acid, dextrose, glycerin, glycine, hypromellose, magnesium chloride, polyquaternium-42, potassium chloride, purified water, sodium borate, sodium chloride, 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 UPTO 10 HRS COMFORT

VISINE<sub>®</sub>

DRY EYE RELIEF

**TIRED EYE** 

LUBRICANT EYE DROPS

**STARTS TO RELIEVE** 

**DRY EYE IN SECONDS** 

Soothes + Revives

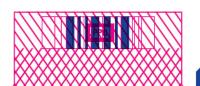
Tired Eyes from

Screen Time

Irritation

**STERILE** 

1/2 FL OZ (15mL)





# TIRED EYE

**LUBRICANT EYE DROPS** 

#### **Drug Facts**

#### Active ingredient Polyethylene glycol 400 1%

**Purpose** Lubricant

Uses • for the temporary relief of burning, irritation, and discomfort due to dryness of the eye or exposure to wind or sun . 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

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

### **Drug Facts**

## Other information

Store at room temperature

## Inactive ingredients

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

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

Caution: Do not use if VISINE® imprinted neckband on bottle is broken or missing.



#### UP TO 10 HRS COMFORT

**DRY EYE RELIEF** TIRED EYE



LUBRICANT EYE DROPS



#### **STARTS TO RELIEVE** DRY EYE IN SECONDS

Soothes + Revives Tired Eyes from Screen Time Irritation

STERILE

1/2 FL 0Z (15mL)

Distributed by: JOHNSON & JOHNSON CONSUMER INC. Skillman, NJ 08558 Active made in Germany © J&JCI 2020 www.visine.com





USA 691229 955

#### VISINE DRY EYE RELIEF EYE DROPS

polyethylene glycol 400 solution/ drops

#### **Product Information**

HUMAN OTC DRUG Product Type Item Code (Source) NDC:69968-0364

OPHTHALMIC **Route of Administration** 

#### **Active Ingredient/Active Moiety**

| Ingredient Name   | Basis of Strength          | Strength         |
|---|----------------------------|------------------|
| <b>Polyethylene Glycol 400</b> (UNII: B697894SGQ) (Polyethylene Glycol 400 - UNII:B697894SGQ) | Polyethylene Glycol<br>400 | 10 mg<br>in 1 mL |

| Ingredient Name scorbic Acid (UNII: PQ6CK8PD0R) oric Acid (UNII: R57ZHV85D4) EXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2) lycerin (UNII: PDC6A3C0OX) lycine (UNII: TE7660XO1C) YPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) lagnesium Chloride (UNII: 02F3473H9O) OLIXETONIUM CHLORIDE (UNII: RNW5AM67C0) otassium Chloride (UNII: 660YQ98I10) VATER (UNII: 059QF0KO0R) odium Borate (UNII: 91MBZ8H3QO) odium Chloride (UNII: 451W47IQ8X) ODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR) |          |
|---|----------|
| eric Acid (UNII: R57ZHV85D4)  EXTROSE, UNSPECIFIED FORM (UNII: IY9 XDZ35W2)  lycerin (UNII: PDC6A3C0OX)  lycine (UNII: TE7660 XO1C)  YPROMELLOSE, UNSPECIFIED (UNII: 3NXW29 V3WO)  lagnesium Chloride (UNII: 02F3473H9O)  OLIXETONIUM CHLORIDE (UNII: RNW5AM67C0)  otassium Chloride (UNII: 660 YQ98 I10)  ATER (UNII: 059QF0KO0R)  odium Borate (UNII: 91MBZ8H3QO)  odium Chloride (UNII: 451W47IQ8X)  | Strength |
| EXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2)  lycerin (UNII: PDC6A3C0OX)  lycine (UNII: TE7660XO1C)  YPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)  lagnesium Chloride (UNII: 02F3473H9O)  OLIXETONIUM CHLORIDE (UNII: RNW5AM67C0)  otassium Chloride (UNII: 660YQ98I10)  YATER (UNII: 059QF0KO0R)  odium Borate (UNII: 91MBZ8H3QO)  odium Chloride (UNII: 451W47IQ8X)  |          |
| lycerin (UNII: PDC6A3C0OX) lycine (UNII: TE7660XO1C) YPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) (agnesium Chloride (UNII: 02F3473H9O) OLIXETONIUM CHLORIDE (UNII: RNW5AM67C0) otassium Chloride (UNII: 660YQ98I10) VATER (UNII: 059QF0KO0R) odium Borate (UNII: 91MBZ8H3QO) odium Chloride (UNII: 451W47IQ8X)  |          |
| lycine (UNII: TE7660XO1C)  YPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)  lagnesium Chloride (UNII: 02F3473H9O)  OLIXETONIUM CHLORIDE (UNII: RNW5AM67C0)  otassium Chloride (UNII: 660YQ98I10)  VATER (UNII: 059QF0KO0R)  odium Borate (UNII: 91MBZ8H3QO)  odium Chloride (UNII: 451W47IQ8X)  |          |
| YPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) (agnesium Chloride (UNII: 02F3473H9O) (DLIXETONIUM CHLORIDE (UNII: RNW5AM67CO) (DLIXETONIUM CHLORIDE (UNII: 660YQ98I1O) (ATER (UNII: 059QF0KOOR) (DIXETONIUM CHLORIDE (UNII: 91MBZ8H3QO) (DIXETONIUM CHLORIDE (UNII: 451W47IQ8X)  |          |
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| OLIXETONIUM CHLORIDE (UNII: RNW5AM67C0) otassium Chloride (UNII: 660 YQ98 I10) VATER (UNII: 059 QF0 KO0 R) odium Borate (UNII: 9 IMBZ8 H3QO) odium Chloride (UNII: 451W47IQ8 X)   |          |
| otassium Chloride (UNII: 660 YQ98 I10) VATER (UNII: 059 QF0 KO0 R) odium Borate (UNII: 9 1MBZ8 H3 QO) odium Chloride (UNII: 451W47 IQ8 X)   |          |
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| odium Borate (UNII: 91MBZ8H3QO) odium Chloride (UNII: 451W47IQ8X)   |          |
| odium Chloride (UNII: 451W47IQ8X)   |          |
|   |          |
| ODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)  |          |
|   |          |
| odium Lactate (UNII: TU7HW0W0QT)  |          |

| Packaging            |  |                         |                       |  |  |  |
|----------------------|--|-------------------------|-----------------------|--|--|--|
| # Item Code          | Package Description  | Marketing Start<br>Date | Marketing End<br>Date |  |  |  |
| NDC:69968-<br>0364-1 | 1 in 1 CARTON  | 04/27/2020              |                       |  |  |  |
| 1                    | 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.