**ROHTO OPTIC GLOW- naphazoline hydrochloride, povidone, propylene glycol liquid**
**The Mentholatum Company**

*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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**Drug Facts**

**Active ingredients**

Naphazoline hydrochloride 0.03%

Povidone 0.5%

Propylene glycol 0.2%

**Purpose**

Naphazoline hydrochloride - Redness reliever

Povidone – Lubricant

Propylene glycol - Lubricant

**Uses**

- relieves redness of the eye due to minor eye irritations
- temporarily relieves burning and irritation due to dryness of the eye

**Warnings**

**For external use only**

**Ask a doctor before use if you have**

narrow angle glaucoma

**When using this product**

- do not touch tip of container to any surface to avoid contamination
- replace cap after each use
- do not use if solution changes color or becomes cloudy
- overuse of this product may produce increased redness of the eye
- pupils may become enlarged temporarily

**Stop use and ask a doctor if**

- you experience eye pain
- changes in vision occur
- redness or irritation of the eyes lasts

- condition worsens or lasts more than 72 hours

**Keep out of reach of children.**

If swallowed, get medical help or contact a Poison Control Center right away.

**Directions**
- put 1 or 2 drops in the affected eye(s) up to 4 times daily
- tightly snap on cap to seal

**Other Safety Information**
- do not store above 25°C (77°F)

**Inactive ingredients**

anhydrous citric acid, boric acid, chlorobutanol, edetate disodium, menthol, polysorbate 80, potassium aspartate, purified water, pyridoxine hydrochloride, sodium borate, sodium citrate, sodium hyaluronate

**Questions?**

**1-877-636-2677** MON-FRI 9 AM to 5 PM (EST)

**Package/Label Principal Display Panel**


# ROHTO OPTIC GLOW

naphazoline hydrochloride, povidone, propylene glycol liquid

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:10742-8160 |
| **Route of Administration** | OPHTHALMIC | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **NAPHAZOLINE HYDROCHLORIDE** (UNII: MZ1131787D) (NAPHAZOLINE - UNII:H231GF11BV) | NAPHAZOLINE HYDROCHLORIDE | 0.3 mg in 1 mL |
| **POVIDONE, UNSPECIFIED** (UNII: FZ989GH94E) (POVIDONE, UNSPECIFIED - UNII:FZ989GH94E) | POVIDONE, UNSPECIFIED | 5 mg in 1 mL |
| **PROPYLENE GLYCOL** (UNII: 6DC9Q167V3) (PROPYLENE GLYCOL - UNII:6DC9Q167V3) | PROPYLENE GLYCOL | 2 mg in 1 mL |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **ANHYDROUS CITRIC ACID** (UNII: XF417D3PSL) | |
| **BORIC ACID** (UNII: R57ZHV85D4) | |
| **CHLOROBUTANOL** (UNII: HM4YQM8WRC) | |
| **EDETATE DISODIUM** (UNII: 7FLD91C86K) | |
| **MENTHOL, UNSPECIFIED FORM** (UNII: L7T10EIP3A) | |
| **POLYSORBATE 80** (UNII: 6OZP39ZG8H) | |
| **POTASSIUM ASPARTATE** (UNII: OC4598NZEQ) | |
| **WATER** (UNII: 059QF0KO0R) | |
| **PYRIDOXINE HYDROCHLORIDE** (UNII: 68Y4CF58BV) | |
| **SODIUM BORATE** (UNII: 91MBZ8H3QO) | |
| **SODIUM CITRATE, UNSPECIFIED FORM** (UNII: 1Q73Q2JULR) | |
| **HYALURONATE SODIUM** (UNII: YSE9PPT4TH) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:10742-8160-1 | 1 in 1 CARTON | 03/26/2021 | |
| **1** | | 13 mL in 1 BOTTLE, WITH APPLICATOR; 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 | 03/26/2021 | |

## Labeler - The Mentholatum Company (002105757)

## Registrant - The Mentholatum Company (002105757)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Rohto-Mentholatum (Vietnam) Co. Ltd. | | 555347535 | manufacture(10742-8160) |

Revised: 2/2023 The Mentholatum Company