**ROHTO ALL-IN-ONE- hypromellose, tetrahydrozoline hydrochloride, zinc sulfate 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**

Hypromellose 0.2%

Tetrahydrozoline HCl 0.05%

Zinc sulfate 0.25%

**Purpose**

Hypromellose - Lubricant

Tetrahydrozoline HCl - Redness reliever

Zinc sulfate - Astringent

**Uses**

- temporarily relieves redness of the eye and discomfort due to
  - minor eyes irritations
  - exposure to wind or sun
- 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 may cause more eye redness
- pupils may become enlarged temporarily

**Stop use and ask a doctor if**

- you feel 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 information***

- store at 20-25°C (68-77°F)

**Inactive ingredients**

boric acid, edetate disodium, menthol, polysorbate 80, purified water, sodium borate

**Questions?**

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

**Package/Label Principal Display Panel**


# ROHTO ALL-IN-ONE

hypromellose, tetrahydrozoline hydrochloride, zinc sulfate liquid

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:10742-8146 |
| **Route of Administration** | OPHTHALMIC | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **HYPROMELLOSE, UNSPECIFIED** (UNII: 3NXW29V3WO) (HYPROMELLOSE, UNSPECIFIED - UNII:3NXW29V3WO) | HYPROMELLOSE, UNSPECIFIED | 2 mg in 1 mL |
| **TETRAHYDROZOLINE HYDROCHLORIDE** (UNII: 0YZT43HS7D) (TETRAHYDROZOLINE - UNII:S9U025Y077) | TETRAHYDROZOLINE HYDROCHLORIDE | 0.5 mg in 1 mL |
| **ZINC SULFATE, UNSPECIFIED FORM** (UNII: 89DS0H96TB) (ZINC CATION - UNII:13S1S8SF37) | ZINC SULFATE, UNSPECIFIED FORM | 2.5 mg in 1 mL |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **BORIC ACID** (UNII: R57ZHV85D4) | |
| **EDETATE DISODIUM** (UNII: 7FLD91C86K) | |
| **MENTHOL, UNSPECIFIED FORM** (UNII: L7T10EIP3A) | |
| **POLYSORBATE 80** (UNII: 6OZP39ZG8H) | |
| **WATER** (UNII: 059QF0KO0R) | |
| **SODIUM BORATE** (UNII: 91MBZ8H3QO) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:10742-8146-1 | 1 in 1 CARTON | 06/21/2021 | |
| **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 | 06/21/2021 | |

## Labeler - The Mentholatum Company (002105757)

## Registrant - The Mentholatum Company (002105757)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Rohto-Mentholatum (Vietnam) Co. Ltd. | | 555347535 | manufacture(10742-8146) |

Revised: 2/2023 The Mentholatum Company