

ROHTO HYDRA- hydroxyethyl cellulose 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.

Drug Facts

Active ingredient

Hydroxyethyl cellulose 0.6%

Purpose

Hydroxyethyl cellulose - Lubricant

Uses

- temporarily relieves discomfort due to minor irritations of the eye or exposure to wind or sun
- lubricates to prevent further irritation or to relieve dryness of the eye

Warnings

For external use only

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
- remove contact lenses before using

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) as needed

Other information

- store at 20-25 °C (68-77°F)

- tightly snap on cap to seal

Inactive ingredients

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

Questions?

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

Principal Display Panel



ROHTO HYDRA

hydroxyethyl cellulose liquid

Product Information

| | | | |
|-------------------------|----------------|--------------------|------------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:10 742-8 148 |
| Route of Administration | OPHTHALMIC | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|---|-----------------|
| HYDROXYETHYL CELLULOSE (2000 MPA.S AT 1%) (UNII: S38J6RZN16) (HYDROXYETHYL CELLULOSE (2000 MPA.S AT 1%) - UNII:S38J6RZN16) | HYDROXYETHYL CELLULOSE (2000 MPA.S AT 1%) | 6 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|-----------------|
| BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) | |
| BORIC ACID (UNII: R57ZHV85D4) | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |
| MENTHOL (UNII: L7T10EIP3A) | |
| POLYSORBATE 80 (UNII: 6OZP39ZG8H) | |
| POTASSIUM CHLORIDE (UNII: 660YQ98I10) | |
| WATER (UNII: 059QF0K00R) | |
| SODIUM BORATE (UNII: 91MBZ8H3QO) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|---|-----------------------------|---------------------------|
| 1 | NDC:10742-8148-1 | 1 in 1 CARTON | 01/03/2011 | |
| 1 | | 13 mL in 1 BOTTLE, DROPPER; 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 | 01/03/2011 | |

Labeler - The Mentholatum Company (002105757)

Revised: 11/2014

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