ROHTO ICE- 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.

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
- 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) 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 ICE

hypromellose, tetrahydrozoline hydrochloride, zinc sulfate liquid

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:10742-8143
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:10742-8143-1	1 in 1 CARTON	09/27/2005	
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	09/27/2005	

Labeler - The Mentholatum Company (002105757)

Registrant - The Mentholatum Company (002105757)

Establishment

Name	Address	ID/FEI	Business Operations
Rohto-Mentholatum (Vietnam) Co. Ltd.		555347535	manufacture(10742-8143)

Revised: 2/2023 The Mentholatum Company