

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

The Mentholatum Company

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

Drug Facts Outline of bottle is actual size.

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Tetrahydrozoline HCl 0.05%.....	Redness Reliever
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Rohto®
Cooling Eye Drops
ALL-IN-ONE

8 SYMPTOM RELIEF*

*Relief from Stinging, Red, Gritty, Watery, Irritated, Burning, Dry, Itchy eyes

Fast Acting
STERILE
0.4 FL OZ (13mL)

Exp [redacted] Lot [redacted]

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CA517002

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

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 Drug	M018	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: 12/2024

The Mentholatum Company