

ROHTO COOL RELIEF- naphazoline hydrochloride, polysorbate 80 liquid
The Mentholatum Company

Drug Facts

Active ingredients

Naphazoline hydrochloride 0.012%

Polysorbate 80 0.2%

Purpose

Naphazoline hydrochloride - Redness reliever

Polysorbate 80 - Lubricant

Uses

- relieves redness of the eye due to minor eye irritations
- for use as a lubricant to prevent further irritation or to relieve dryness of the eye
- for protection against further irritation

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

- do not store above 25°C (77°F)

Inactive ingredients

alcohol (0.1%), benzalkonium chloride, boric acid, chlorobutanol, edetate disodium, menthol, 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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ROHTO®
Cooling Eye Drops
COOL RELIEF

3-IN-1
Relieves Redness + Prevents + Protects from Further Irritation

With CoolSense™ Technology

110+ TRUSTED YEARS

Supporting Your Eye Health Around the World

Fast Acting
STERILE
0.4 FL OZ (13mL)

soothes up to 8 hrs. with CoolSense™ Technology

Exp Lot

6 mm

9.91 mm

3 10742 01074 9

Rohto®
Cooling Eye Drops
COOL RELIEF

Global OTC Eye Care Brand

Proprietary formula cools and soothes eyes instantly for added comfort.

Rohto® - Feel It Working!

Child-resistant cap. Retain carton for complete information.

Use only if **ROHTO®** imprinted inner pouch is intact at time of purchase.

Distributed by:
The Mentholatum Company
Orchard Park, NY 14127
Made in Vietnam ©2020

TO CLOSE AND CLIP: PUSH DOWN AND CLIP

TO OPEN: PUSH DOWN AND TWIST OPEN

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1 2 3 4
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13 14 15 16

CA453005

ROHTO COOL RELIEF

naphazoline hydrochloride, polysorbate 80 liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10742-8141
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NAPHAZOLINE HYDROCHLORIDE (UNII: MZ1131787D) (NAPHAZOLINE - UNII:H231GF11BV)	NAPHAZOLINE HYDROCHLORIDE	0.12 mg in 1 mL
POLYSORBATE 80 (UNII: 6OZP39ZG8H) (POLYSORBATE 80 - UNII:6OZP39ZG8H)	POLYSORBATE 80	2 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	1 mg in 1 mL
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
BORIC ACID (UNII: R57ZHV85D4)	
CHLOROBUTANOL (UNII: HM4YQM8WRC)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
WATER (UNII: 059QF0KO0R)	
SODIUM BORATE (UNII: 91MBZ8H3QO)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10742-8141-1	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(10742-8141)

Revised: 12/2024

The Mentholatum Company