LABEL: ROHTO COOL- naphazoline hydrochloride, polysorbate 80 liquid

VIEW PACKAGE PHOTOS



NDC Code(s): 10742-8142-1
Packager: The Mentholatum Company

Category: HUMAN OTC DRUG LABEL
DEA Schedule: None
Marketing Status: OTC monograph final

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 LABEL INFORMATION

Updated October 4, 2021

If you are a consumer or patient please visit this version.

CLOSE ALL SECTIONS

ACTIVE INGREDIENTS

Naphazoline hydrochloride 0.012%

Polysorbate 80 0.2%

CLOSE

PURPOSE

Naphazoline hydrochloride - Redness reliever

Polysorbate 80 - Lubricant

CLOSE

USES

relieves redness of the eye due to minor eye irritations
temporarily relieves burning and irritation due to dryness of the eye

CLOSE

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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.

CLOSE

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)

CLOSE

INACTIVE INGREDIENTS

alcohol (0.1%), benzalkonium chloride, boric acid, chlorobutanol, edetate disodium, menthol, purified water, sodium borate

CLOSE

QUESTIONS?

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

CLOSE

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL

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CLOSE

INGREDIENTS AND APPEARANCE

ROHTO COOL
naphazoline hydrochloride, polysorbate 80 liquid

PRODUCT INFORMATION			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:10742-8142
Route of Administration	OPHTHALMIC		

ACTIVE INGREDIENT/ACTIVE MOIETY		
Ingredient Name	**Basis of Strength**	**Strength**
NAPHAZOLINE HYDROCHLORIDE (UNII: MZ1131787D) (NAPHAZOLINE - UNII:H231GF11BV)	NAPHAZOLINE HYDROCHLORIDE	.12 mg in 1 mL
POLYSORBATE 80 (UNII: 6OZP39ZG8H) (POLYSORBATE 80 - UNII:6OZP39ZG8H)	POLYSORBATE 80	2 mg in 1 mL

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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:10742-8142-1	1 in 1 CARTON	08/21/2001	
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	08/21/2001	

LABELER - THE MENTHOLATUM COMPANY (002105757)

REGISTRANT - THE MENTHOLATUM COMPANY (002105757)

ESTABLISHMENT

NAME	ADDRESS	ID/FEI	BUSINESS OPERATIONS
Rohto-Mentholatum (Vietnam) Co. Ltd.		555347535	MANUFACTURE(10742-8142)

CLOSE

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CLOSE ALL SECTIONS

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SAFETY

Report Adverse Events, FDA Safety Recalls, Presence in Breast Milk

RELATED RESOURCES

Medline Plus, Clinical Trials, PubMed, Biochemical Data Summary

MORE INFO ON THIS DRUG

View Labeling Archives, RxNorm, Get Label RSS Feed, View NDC Code(s)NEW!



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