

**ROHTO COOL- naphazoline hydrochloride, polysorbate 80 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.*

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**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
- 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 top 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?

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

## Package/Label Principal Display Panel



## ROHTO COOL

naphazoline hydrochloride, polysorbate 80 liquid

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:10742-8142
<b>Route of Administration</b>	OPHTHALMIC		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>NAPHAZOLINE HYDROCHLORIDE</b> (UNII: MZ1131787D) (NAPHAZOLINE - UNII:H231GF11BV)	NAPHAZOLINE HYDROCHLORIDE	.12 mg in 1 mL
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H) (POLYSORBATE 80 - UNII:6OZP39ZG8H)	POLYSORBATE 80	2 mg in 1 mL

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>ALCOHOL</b> (UNII: 3K9958V90M)	1 mg in 1 mL
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7)	
<b>BORIC ACID</b> (UNII: R57ZHV85D4)	
<b>CHLOROBUTANOL</b> (UNII: HM4YQM8WRC)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>MENTHOL, UNSPECIFIED FORM</b> (UNII: L7T10EIP3A)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>SODIUM BORATE</b> (UNII: 91MBZ8H3QO)	

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
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**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph final	part349	08/21/2001	

**Labeler** - The Mentholatum Company (002105757)

Revised: 3/2017

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