ROHTO COOL- 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
- 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

- 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 to 5 PM (EST)

Package/Label Principal Display Panel

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	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:10742-8142-1	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 Drug	M018	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)

Revised: 12/2024

The Mentholatum Company