

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

Drug Facts - Rohto Cool Max

Active ingredients

Naphazoline hydrochloride 0.03%

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
- 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 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, potassium aspartate, 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 MAX

naphazoline hydrochloride, polysorbate 80 liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10742-8159
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NAPHAZOLINE HYDROCHLORIDE (UNII: MZ1131787D) (NAPHAZOLINE - UNII:H231GF11BV)	NAPHAZOLINE HYDROCHLORIDE	0.3 mg in 1 mL
POLYSORBATE 80 (UNII: 6OZP39ZG8H) (POLYSORBATE 80 - UNII:6OZP39ZG8H)	POLYSORBATE 80	2 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
BORIC ACID (UNII: R57ZHV85D4)	
CHLOROBUTANOL (UNII: HM4YQM8WRC)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
POTASSIUM ASPARTATE (UNII: OC4598NZEQ)	
WATER (UNII: 059QF0KOOR)	
SODIUM BORATE (UNII: 91MBZ8H3QO)	
ALCOHOL (UNII: 3K9958V90M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10742-8159-1	1 in 1 CARTON	05/05/2014	
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	05/05/2014	

Labeler - The Mentholatum Company (002105757)

Registrant - The Mentholatum Company (002105757)

Establishment

Name	Address	ID/FEI	Business Operations
The Mentholatum Company		002105757	label(10742-8159)

Establishment

Name	Address	ID/FEI	Business Operations
Rohto-Mentholatum (Vietnam) Co. Ltd.		555347535	manufacture(10742-8159)

Revised: 12/2024

The Mentholatum Company