ROHTO COOL- naphazoline hydrochloride, polysorbate liquid
Rohto Pharmaceutical Co Ltd

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 Facts

Active ingredients

Naphazoline hydrochloride 0.012%

Polysorbate 80 0.2%

Purpose

Naphazoline hydrochloride - Redness reliever

Polysorbate - 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?

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

Package/Label Principal Display Panel

ROHTO COOL
naphazoline hydrochloride, polysorbate liquid

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:66613-8142
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)	
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:66613-8142-1	1 in 1 CARTON	08/21/2001	
1		13 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:66613-8142-2	7 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2013	

Marketing Information

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

Labeler - Rohto Pharmaceutical Co Ltd (690573662)

Revised: 10/2016 Rohto Pharmaceutical Co Ltd