

ROHTO OPTIC GLOW- naphazoline hydrochloride, povidone, propylene glycol liquid

The Mentholatum Company

Drug Facts - Rohto Optic Glow

Active ingredients

Naphazoline hydrochloride 0.03%

Povidone 0.5%

Propylene glycol 0.2%

Purpose

Naphazoline hydrochloride - Redness reliever

Povidone - Lubricant

Propylene glycol - 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 of this product may produce increased redness of the eye
- pupils may become enlarged temporarily

Stop use and ask a doctor if

- you experience 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 Safety Information

- do not store above 25°C (77°F)

Inactive ingredients

anhydrous citric acid, boric acid, chlorobutanol, edetate disodium, menthol, polysorbate 80, potassium aspartate, purified water, pyridoxine hydrochloride, sodium borate, sodium citrate, sodium hyaluronate

Questions?

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

Package/Label Principal Display Panel



ROHTO OPTIC GLOW

naphazoline hydrochloride, povidone, propylene glycol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10742-8160
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
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E) (POVIDONE, UNSPECIFIED - UNII:FZ989GH94E)	POVIDONE, UNSPECIFIED	5 mg in 1 mL
PROPYLENE GLYCOL (UNII: 6DC9Q167V3) (PROPYLENE GLYCOL - UNII:6DC9Q167V3)	PROPYLENE GLYCOL	2 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
BORIC ACID (UNII: R57ZHV85D4)	
CHLOROBUTANOL (UNII: HM4YQM8WRC)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POTASSIUM ASPARTATE (UNII: OC4598NZEQ)	
WATER (UNII: 059QF0KO0R)	
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV)	
SODIUM BORATE (UNII: 91MBZ8H3QO)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10742-8160-1	1 in 1 CARTON	03/26/2021	
1		13 mL in 1 BOTTLE, WTH 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	03/26/2021	

Labeler - The Mentholatum Company (002105757)

Registrant - The Mentholatum Company (002105757)

Establishment

Name	Address	ID/FEI	Business Operations
Rohto-Mentholatum (Vietnam) Co. Ltd.		555347535	manufacture(10742-8160)