ROHTO HYDRA- hydroxyethyl cellulose (2000 mpa.s at 1%) 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.

Drug Facts

Active ingredient

Hydroxyethyl cellulose 0.6%

Purpose

Hydroxyethyl cellulose - Lubricant

Uses

- temporarily relieves discomfort due to minor irritations of the eye or exposure to wind or sun
- lubricates to prevent further irritation or to relieve dryness of the eye

Warnings

For external use only

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
- 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) as needed

Other information

• store at 20-25 °C (68-77°F)

tightly snap on cap to seal

Inactive ingredients

benzalkonium chloride, boric acid, edetate disodium, menthol, polysorbate 80, potassium chloride, purified water, sodium borate, sodium chloride

Questions?

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

Principal Display Panel



ROHTO HYDRA hydroxyethyl cellulose liquid Product Information Product Type HUMAN OTC DRUG LABEL Item Code (Source) NDC:10742-8148 Route of Administration OPHTHALMIC DEA Schedule

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
HYDROXYETHYL CELLULOSE (2000 MPA.S AT 1%) (HYDROXYETHYL CELLULOSE (2000 MPA.S AT 1%))	HYDROXYETHYL CELLULOSE (2000 MPA.S AT 1%)	6 mg in 1 mL		

Inactive Ingredients					
Ingredient Name	Strength				
BENZALKONIUM CHLORIDE					
BORIC ACID					
EDETATE DISO DIUM					
MENTHO L					
POLYSORBATE 80					
POTASSIUM CHLORIDE					
WATER					
SODIUM BORATE					
SO DIUM CHLO RIDE					

I	Packaging	ackaging					
	# Item Code	Package Description	Marketing Start Date	Marketing End Date			
	NDC:10742- 8148-1	1 in 1 CARTON	0 1/0 3/20 11				
	1	13 mL in 1 BOTTLE, DROPPER; Combination Product Type = C112160					

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph final	part349	0 1/0 3/20 11			

Labeler - The Mentholatum Company (002105757)

Revised: 11/2014 The Mentholatum Company