ROHTO DRY-AID- povidone, propylene glycol 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

Povidone 0.68%

Propylene glycol 0.3%

Purpose

Povidone - Lubricant

Propylene glycol - Lubricant

Uses

- temporarily relieves burning and irritation due to dryness of the eye
- protects against 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

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
- tightly snap on cap to seal

Other information

do not freeze

Inactive ingredients

boric acid, calcium chloride, edetate disodium, magnesium sulfate, menthol, PEG-10 castor oil, poloxamer, polyaminopropyl biguanide, polyoxyl stearate, purified water, sesame oil, sodium borate

Questions?

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

Principal Display Panel



povidone, propylene glycol liquid

Product Information

Product Type HUMAN OTC DRUG	Item Code (Source)	NDC:10742-8162
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Route of Administration OPHTHALMIC

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E) (POVIDONE, UNSPECIFIED - UNII:FZ989GH94E)	POVIDONE, UNS PECIFIED	6.8 mg in 1 mL	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3) (PROPYLENE GLYCOL - UNII:6DC9Q167V3)	PROPYLENE GLYCOL	3 mg in 1 mL	

Inactive Ingredients	
Ingredient Name	Strength
BORIC ACID (UNII: R57ZHV85D4)	
CALCIUM CHLORIDE (UNII: M4I0D6VV5M)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
MAGNESIUM SULFATE ANHYDROUS (UNII: ML30MJ2U7I)	
RACEMENTHOL (UNII: YS08XHA860)	
POLYOXYL 35 CASTOR OIL (UNII: 6D4M1DAL6O)	
PEG/PPG-105/5 COPOLYMER (UNII: 52901V8XAR)	
POLIHEXANIDE HYDROCHLORIDE (UNII: 4XI6112496)	
POLYOXYL 40 STEARATE (UNII: 13A4J4NH9I)	
WATER (UNII: 059QF0KO0R)	
SESAME OIL (UNII: QX10HYY4QV)	
SODIUM BORATE (UNII: 91MBZ8H3QO)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10742- 8162-1	1 in 1 CARTON	01/01/2017	
1		10 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		
2	NDC:10742- 8162-2	2 in 1 CARTON	01/01/2017	
2		10 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part349	01/01/2017	

Labeler - The Mentholatum Company (002105757)

Registrant - The Mentholatum Company (002105757)

Establishment				
Name	Address	ID/FEI	Business Operations	
Rohto Pharmaceutical Co. Ltd.		696604024	manufacture(10742-8162)	

Revised: 2/2023 The Mentholatum Company