ROHTO PRESERVATIVE FREE 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
- do not reuse
- once opened, discard
- do not use if solution changes color or becomes cloudy

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 persists for more than 72 hours

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- twist tab completely to remove; do not pull tab off

- instill 1 or 2 drops in the affected eye(s) as needed
- discard container

Other information

- use only if single-use container is intact
- do not freeze

Inactive ingredients

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

Questions?

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

Principal Display Panel

ROHTO PRESERVATIVE FREE DRY AID

povidone, propylene glycol liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:10742-8161
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E) (POVIDONE, UNSPECIFIED - UNII:FZ989GH94E)	POVIDONE, UNSPECIFIED	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)	
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:10742-8161-1	30 in 1 CARTON	06/03/2022	
1		0.5 mL in 1 VIAL, SINGLE-USE; 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	06/03/2022	

Labeler - The Mentholatum Company (002105757)