

CVS SINGLE USE LUBRICANT EYE DROPS- polyethylene glycol 400, and propylene glycol solution/ drops

Bershtel Enterprises LLC

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.

Active ingredients Purpose Polyethylene glycol 400 0.4%.....Lubricant Propylene glycol 0.3%.....Lubricant

Use For the temporary relief of burning and irritation due to 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

Stop use and ask a doctor if you feel eye pain changes in vision occurredness or irritation of the eye(s) get worse, persists 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.

Ophthalmic - Administration to the external eye.

Directions Instill 1 or 2 drops in the affected eye(s) as needed.

Other information Store at room temperature. Protect from light.

Inactive ingredients aminomethylpropanol, boric acid, hydrochloric acid, hydroxyethyl cellulose, potassium chloride, sodium chloride, sodium hydroxide, sorbitol, water for injection



CVS SINGLE USE LUBRICANT EYE DROPS

polyethylene glycol 400, and propylene glycol solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10564-6553
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3) (PROPYLENE GLYCOL - UNII:6DC9Q167V3)	PROPYLENE GLYCOL	3 mg
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ) (POLYETHYLENE GLYCOL 400 - UNII:B697894SGQ)	POLYETHYLENE GLYCOL 400	4 mg

Inactive Ingredients

Ingredient Name	Strength
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
BORIC ACID (UNII: R57ZHV85D4)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0K00R)	
POTASSIUM CHLORIDE (UNII: 660YQ98110)	
SODIUM CHLORIDE (UNII: 451W471Q8X)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10564-6553-0	1 in 1 CARTON; Type 0: Not a Combination Product	01/21/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part349	01/21/2016	

Labeler - Bershtel Enterprises LLC (066659129)

Revised: 3/2018

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