MAJOR LIQUITEARS- polyvinyl alcohol solution/ drops
A-S Medication Solutions

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 ingredient Purpose

Polyvinyl Alcohol 1.4%..... Lubricant

Uses

- to prevent further irritation
- to relieve dryness of the eye

Warnings

Do not use

- if solution changes color or becomes cloudy

When using this product

- do not touch tip of container to any surface to avoid contamination
- replace cap after each use

Stop use and ask a doctor if

- you experience eye pain, changes in vision, continued redness or irritation of the eye
- 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

- instill 1 to 2 drops in the affected eye(s) as needed

Other information

- store at 15°-25°C (59°-77°F)
- keep tightly closed

Inactive ingredients

benzalkonium chloride, dibasic sodium phosphate hydrate, edetate disodium hydrate, monobasic sodium phosphate dihydrate, purified water, sodium chloride

Distributed by:

Major Pharmaceuticals

31778 Enterprise Drive

Livonia, MI 48150 USA

Made in Korea

HOW SUPPLIED

Product: 50090-3158

NDC: 50090-3158-0 15 mL in a BOTTLE, DROPPER / 1 in a CARTON

Polyvinyl Alcohol

MAJOR LIQUITEARS

polyvinyl alcohol solution/ drops

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50090-3158(NDC:0904-6492)
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
POLYVINYL ALCOHOL (UNII: 532B59J990) (POLYVINYL ALCOHOL - UNII:532B59J990)	POLYVINYL ALCOHOL	14 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
SODIUM PHOSPHATE, DIBASIC, MONOHYDRATE (UNII: BWZ7K44R51)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
SODIUM PHOSPHATE, MONOBASIC, DIHYDRATE (UNII: 5QWK665956)	
WATER (UNII: 059QF0KO0R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50090-3158-0	1 in 1 CARTON	10/10/2017	
1		15 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	09/17/2015	

Labeler - A-S Medication Solutions (830016429)

Establishment

Name	Address	ID/FEI	Business Operations
A-S Medication Solutions		830016429	RELABEL(50090-3158)

Revised: 1/2020 A-S Medication Solutions