

LIQUITEARS - polyvinyl alcohol solution/ drops
H.J. Harkins Company, Inc.

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.

Artificial Tears Solution Drug Facts

Active ingredient

Polyvinyl Alcohol 1.4%

Purpose

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 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° - 30°C (59° - 86°F)
- keep tightly closed

Inactive ingredients

dibasic sodium phosphate, edetate disodium, monobasic sodium phosphate, sodium chloride, purified water. Phosphoric acid and/or sodium hydroxide may be added to adjust pH. PRESERVATIVE ADDED: benzalkonium chloride 0.01%

Questions ?

Serious side effects associated with use of this product may be reported to 1800-323-0000

*MAJOR LIQUITEARS IS NOT MANUFACTURED OR DISTRIBUTED BY ALLERGAN, INC. OWNER OF THE REGISTERED TRADEMARK, LIQUIFILM TEARS®.

Package/Label Principal Display Panel

52959-041-00 RX Only: #XXXXXXXX #XXX CAUTION: Federal law PROHIBITS the transfer of this drug to anyone other than the person to whom prescribed and prohibits dispensing without a prescription unless OTC. See outsert for add'l RX info KEEP OUT OF REACH OF CHILDREN. Store in a cool dry place 68 to 77 degrees F.

POLYVIN.ALCOH.1.4%EYE DRPS OTC

Lot #: PAE53M
Mfg: MAJOR
Exp: 06/10 Compare to: Liquifilm Tears
Mfg Livonia, MI Mfg. NDC: 0904-5017-35
Loc.: Pill ID: Drops

Take as directed by your Doctor or
See outsert for usual dosage information

POLYVIN.ALCOH.1.4%EYE DRPS OTC	
52959-041-00	Qty 15ml
06/10	Lot PAE53M
Liquifilm Tears	0904-5017-35

POLYVIN.ALCOH.1.4%EYE DRPS OTC	
52959-041-00	Qty 15ml
06/10	Lot PAE53M
Liquifilm Tears	0904-5017-35

POLYVIN.ALCOH.1.4%EYE DRPS OTC	
52959-041-00	Qty 15ml
06/10	Lot PAE53M
Liquifilm Tears	0904-5017-35

POLYVIN.ALCOH.1.4%EYE DRPS OTC	
52959-041-00	Qty 15ml
06/10	Lot PAE53M
Liquifilm Tears	0904-5017-35

Repack: HJ Harkins Co., Inc. Nipomo, CA 93444
Dispense in tight, child & light-resistant container per USP

MAJOR®

NDC 0904-5017-35

LiquiTears

Polyvinyl Alcohol 1.4%

Lubricant Eye Drops (Sterile)

Relieves Burning due to Dryness of the Eye

Compare to Active Ingredient of Liquifilm Tears®*

1/2 FL. OZ. (15 mL)

Repacked by:

H.J. Harkins Company, Inc.

Grover Beach, CA 93433

LIQUITEARS

polyvinyl alcohol solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52959-041(NDC:0904-5017)
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
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JIH2SW)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WATER (UNII: 059QF0KO0R)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52959-041-00	15 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part349	12/09/2011	

Labeler - H.J. Harkins Company, Inc. (147681894)**Registrant** - Bausch & Lomb Incorporated (196603781)**Establishment**

Name	Address	ID/FEI	Business Operations
Bausch & Lomb Incorporated		807927397	MANUFACTURE

Revised: 3/2012

H.J. Harkins Company, Inc.