ARTIFICIAL TEARS- polyvinyl alcohol solution/ drops
Cardinal Health

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

- temporary relieve of burning and irritation due to 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

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
- replace cap after use

Inactive ingredients

dibasic sodium phosphate, edetate disodium, monobasic sodium phosphate,

purified water, sodium chloride. 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

DO NOT USE IF IMPRINTED "Protective Seal" WITH YELLOW IS NOT INTACT.

Package/Label Principal Display Panel

NDC 37205-137-05

LEADER®

Compare to Liquifilm Tears®* active ingredient*

Artificial Tears Solution

Polyvinyl Alcohol 1.4%

Lubricant Eye Drops

(Sterile)

FOR USE IN THE EYES ONLY

SATISFACTION GUARANTEED 1/2 FL. OZ. (15 mL)

ARTIFICIAL TEARS

polyvinyl alcohol solution/ drops

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:37205-137

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:37205-137-05	15 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part349	11/15/2011	

Labeler - Cardinal Health (097537435)

Registrant - Bausch & Lomb Incorporated (196603781)

Establishment

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

Revised: 11/2011 Cardinal Health