LEADER ARTIFICIAL TEARS 15 ML- polyvinyl alcohol, povidone solution/ drops Cardinal Health

Leader Artificial Tears 15mL (PLD)

Active Ingredients

Polyvinyl alcohol 0.5%

Povidone 0.6%

Purposes

Lubricant

Lubricant

Uses

- for use as a protectant against further irritation or to relieve dryness of the eye
- for the temporary relief of discomfort due to minor irritations of the eye, or to exposure to wind or sun

Warnings

For external use only

Do not use this product if

• solution changes color or becomes cloudy

When using this product

- remove contact lens before using
- to avoid contamination, do not touch tip of container to any surface
- replace cap after using. Keep container tightly closed.

Stop use and ask a doctor if you experience

- eye pain
- changes in vision
- continued redness or irritation of the eye or if the condition worsens or persists for more than 72 hours

Keep out of the reach of children.

if accidentally swallowed, get medical help or contact Poison Control Center (1-800-222-1222) immediately.

Directions

- instill 1 or 2 drops in the affected eye(s) as needed
- children under 6 years of age: ask a doctor

Other Information

• store at 15°-30°C (59°-86°F)

Inactive Ingredients

benzalkonium chloride, dextrose, edetate disodium, potassium chloride, purified water, sodium bicarbonate, sodium chloride, sodium citrate, sodium phosphate dibasic, sodium phosphate monobasic

Questions or comments?

Call 1-888-527-4276

Leader Artificial Tears 15mL



LEADER ARTIFICIAL TEARS 15 ML

polyvinyl alcohol, povidone solution/ drops

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0011
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990) (POLYVINYL ALCOHOL, UNSPECIFIED - UNII:532B59J990)	POLYVINYL ALCOHOL, UNSPECIFIED	0.5 g in 100 mL	

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Inactive Ingredients			
Ingredient Name	Strength		
SODIUM BICARBONATE (UNII: 8MDF5V39QO)			
SODIUM CHLORIDE (UNII: 451W47IQ8X)			
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)			
SODIUM PHOSPHATE, MONOBASIC, ANHYDROUS (UNII: KH7I04HPUU)			
DEXTROSE (UNII: IY9XDZ35W2)			
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)			
EDETATE DISODIUM (UNII: 7FLD91C86K)			
WATER (UNII: 059QF0KO0R)			
SODIUM CITRATE (UNII: 1Q73Q2JULR)			
POTASSIUM CHLORIDE (UNII: 660YQ98I10)			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000- 0011-1	1 in 1 BOX	07/03/2019	
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 Drug	M018	07/03/2019	

Labeler - Cardinal Health (063997360)

Registrant - KC Pharmaceuticals, Inc. (174450460)

Establishment			
Name	Address	ID/FEI	Business Operations
KC Pharmaceuticals, Inc.		174450460	manufacture(70000-0011) , pack(70000-0011) , label(70000-0011)

Revised: 12/2023 Cardinal Health