LEADER ADVANCED FORMULA- dextran70, polyethylene glycol, povidone, tetrahydrozoline hcl solution 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.

Active ingredients	Purpose
Dextran 70 0.1%	Lubricant
Polyethylene glycol 400 1%	Lubricant
Povidone 1%	Lubricant
Tetrahydrozoline HCL 0.05%	Redness reliever

Uses

- for the relief of redness of the eyes due to minor eye irritations
- for use as a protectant against further irritation or to relieve dryness of the eye

Warnings

Ask a doctor before use if you have narrow angle glaucoma

When using this product

- pupils may become enlarged temporarily
- overuse may cause more eye redness
- remove contact lenses before using
- do not use if this solution changes color or becomes cloudy
- 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 feel eye pain
- changes in vision occur
- redness or irritation of the eye lasts
- condition worsens or lasts more than 72 hours

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of the reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- put 1 to 2 drops in the affected eye(s) up to 4 times daily
- children under 6 years of age: ask a doctor

Other information

some users may experience a brief tingling sensation store at 15° to 25°C (59° to 77°F)

Inactive ingredients:

benzalkonium chloride, boric acid, edetate disodium, purified water, sodium chloride, and sodium

DISTRIBUTED BY CARDINAL HEALTH

DUBLIN, OHIO 43017

CIN 3256021

www.myleader.com

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Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37205-224
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
DEXTRAN 70 (UNII: 7SA290 YK68) (DEXTRAN 70 - UNII:7SA290 YK68)	DEXTRAN 70	1 mg in 1 mL	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ) (POLYETHYLENE GLYCOL 400 - UNII:B697894SGQ)	POLYETHYLENE GLYCOL 400	10 mg in 1 mL	
PO VIDONES (UNII: FZ989GH94E) (PO VIDONE - UNII:FZ989GH94E)	POVIDONES	10 mg in 1 mL	
TETRAHYDRO ZOLINE HYDRO CHLO RIDE (UNII: 0 YZT43HS7D) (TETRAHYDRO ZOLINE - UNII:S9 U0 25 Y0 77)	TETRAHYDROZOLINE HYDROCHLORIDE	0.5 mg in 1 mL	

Inactive Ingredients		
Ingredient Name	Strength	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)		
BORIC ACID (UNII: R57ZHV85D4)		
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)		
WATER (UNII: 059QF0KO0R)		
SODIUM CHLORIDE (UNII: 451W47IQ8X)		
SODIUM BORATE (UNII: 91MBZ8H3QO)		

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:37205-224-05	1 in 1 CARTON	11/29/2016	
1	15 mL in 1 BOTTLE; 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	0 1/0 4/20 12	

Labeler - CARDINAL HEALTH (097537435)

Revised: 11/2016 CARDINAL HEALTH