LEADER DRY EYE RELIEF - dextran 70 solution
HANLIM PHARM. CO., LTD.

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.

Drug Facts

Active Ingredients Purpose

Dextran 70 (0.1%).....(Lubricant)

Hypromellose 2910 (0.3%).....(Lubricant)

Uses

- for the temporary relief of burning and irritation of the eye and for use as a protectant against further irritation.
- 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: If this solution changes color or becomes cloudy or if you are sensitive to any ingredient in this product.

When using this product

- remove contact lenses before using
- 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 pain
- changes in vision occur
- redness or irritation of the eye gets worse 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

- Instill 1 or 2 drops in the affected eye(s) as needed.
- Store at room temperature

Inactive Ingredients: Benzalkonium Chloride, Potassium Chloride, Disodium Chloride, Sodium Borate, Sodium Chloride, Boric Acid, Sterile Water, Purified Water, Sodium Chloride, and Sodium Citrate

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LEADER DRY EYE RELIEF

dextran 70 solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:11716-9637
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DEXTRAN 70 (UNII: 7SA290YK68) (DEXTRAN 70 - UNII:7SA290YK68)	DEXTRAN 70	0.001 mL in 1 mL
HYPROMELLOSE 2910 (4000 CPS) (UNII: RN3152OP35) (HYPROMELLOSE 2910 (4000 CPS) - UNII:RN3152OP35)	HYPROMELLOSE 2910 (4000 CPS)	0.003 mL in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SODIUM BORATE (UNII: 91MBZ8H3QO)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
BORIC ACID (UNII: R57ZHV85D4)	
WATER (UNII: 059QF0KO0R)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:11716-9637-7	1 in 1 CARTON		
1		15 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part349	07/12/2010	

Labeler - HANLIM PHARM. CO., LTD. (687986034)

Revised: 7/2010 HANLIM PHARM. CO., LTD.