FREDS DRY EYE RELIEF - glycerin 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
Glycerin 0.2%	Lubricant
Polyethylene Glycol 400 1%	Lubricant
Hypromellose 0.2%	Lubricant

Uses
- for the temporary relief of burning and irritation due to dryness of the eye
- for protection against further irritation

Warnings

For external use only

When using this product
- 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 15º to 25ºC (59º to 77ºF)

Inactive ingredients: ascorbic acid, benzalkonium chloride, boric acid, dextrose, disodium phosphate, glycine, magnesium chloride, potassium chloride, purified water,

sodium borate, sodium chloride, sodium citrate, and sodium lactate

Distributed by: Fred's Inc.

4300 New Getwell Rd.
Memphis, TN 38118

www.fredsinc.com

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FREDS DRY EYE RELIEF

glycerin solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:11716-1189
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	0.002 mL in 1 mL
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ) (POLYETHYLENE GLYCOL 400 - UNII:B697894SGQ)	POLYETHYLENE GLYCOL 400	0.01 mL in 1 mL
HYPROMELLOSES (UNII: 3NXW29V3WO) (HYPROMELLOSES - UNII:3NXW29V3WO)	HYPROMELLOSES	0.002 mL in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
BORIC ACID (UNII: R57ZHV85D4)	
DEXTROSE (UNII: IY9XDZ35W2)	
GLYCINE (UNII: TE7660XO1C)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
WATER (UNII: 059QF0KO0R)	
SODIUM BORATE (UNII: 91MBZ8H3QO)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SODIUM LACTATE (UNII: TU7HW0W0QT)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:11716-1189-9	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	12/06/2010	

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

Registrant - UNITED EXCHANGE CORP. (840130579)

Establishment

Name	Address	ID/FEI	Business Operations
HANLIM PHARM. CO., LTD.		687986034	manufacture

Revised: 12/2010 HANLIM PHARM. CO., LTD.