

SHOPKO 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
Hypromellose 0.2%	Lubricant
Polyethylene glycol 400 1%	Lubricant

Uses

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

When using this product

- remove contact lenses before using
- do not use if this solution changes color or become 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) as needed
- 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: 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



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SHOPKO DRY EYE RELIEF

glycerin solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11716-1629
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	0.002 mL in 1 mL
HYPROMELLOSE (UNII: 3NXW29V3WO) (HYPROMELLOSE - UNII:3NXW29V3WO)	HYPROMELLOSE	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

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: 059QF0K00R)	
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:11716-1629-3	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	08/12/2010	

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

Registrant - UNITED EXCHANGE CORP. (840130579)

Establishment

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