LEADER EYE ITCH RELIEF DROPS - ketotifen fumarate solution/ drops
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 ingredient Purpose

Ketotifen (0.025%).....Antihistamine

(Equivalent to ketotifen fumarate 0.035%)

Use

Temporarily relieves itchy eyes due to pollen, ragweed, grass, animal hair and dander.

Warnings

Do not use
- if solution changes color or becomes cloudy
- if you are sensitive to any ingredient in this product
- to treat contact lens related irritation

When using this product
- do not touch tip of container to any surface to avoid contamination
- remove contact lenses before use
- wait at least 10 minutes before reinserting contact lenses after use
- replace cap after each use

Stop use and ask a doctor if you experience any of the following:
- eye pain
- changes in vision
- redness of the eye
- itching worsens or lasts for more than 72 hours

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions
- Adults and children 3 years of age and older: Put 1 drop in the affected eye(s) twice daily, every 8-12 hours, no more than twice per day
- Children under 3 years of age: Consult a doctor

Other information
- Only for use in the eye
- Store between 20°-25°C (68° to 77°F) (See USP controlled Room Temperature)
- Do not use if cap seal ring is broken

Inactive ingredients

benzalkonium chloride 0.01%, glycerol, sodium hydroxide and/or hydrochloric acid, and water for injection

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LEADER EYE ITCH RELIEF DROPS

ketotifen fumarate solution/ drops

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:11716-1163
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
KETOTIFEN FUMARATE (UNII: HBD503WORO) (KETOTIFEN - UNII:X49220T18G)	KETOTIFEN FUMARATE	0.345 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11716-1163-7	1 in 1 CARTON		
1		5 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part349	04/21/2010	

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

Registrant - UNITED EXCHANGE CORP. (840130579)

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