EYES IRRITATION RELIEF- polyvinyl alcohol and povidone and tetrahydrozoline hydrochloride liquid
Cardinal Health, 110 dba LEADER

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.

Sterile Eyes Irritation Relief Triple Action

Drug Facts

Active ingredients

Polyvinyl alcohol 0.5%

Active ingredients

Povidone 0.6%

Purpose

Lubricant

Active ingredient

Tetrahydrozoline hydrochloride 0.05%

Purpose

Redness reliever

Uses

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

Warnings

For external use only

Do not use if

solution changes color or becomes cloudy.

Ask a doctor before use if you have

narrow angle glaucoma.

When using this product

- to avoid contamination, do not touch tip to any surface
- replace cap after using
- overuse may produce increased redness of the eye
- pupils may become enlarged temporarily

Stop use & ask a doctor if

- you experience eye pain
- you experience changes in vision
- you experience continued redness or irritation of the eye
- the condition worsens
- symptoms last for more than 72 hours

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center(1-800-222-1222) right away.

Directions

Instill 1 to 2 drops in the affected eye(s) up to four times daily.

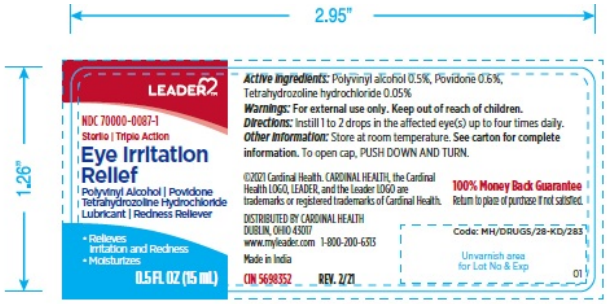
Other information

- store at room temperature
- remove contact lenses before using

Inactive ingredients

Benzalkonium Chloride, Disodium Hydrogen Phosphate Anhydrous, Disodium Edetate, Mannitol , Potassium Chloride, Purified Water, Sodium dihydrogen Phosphate Dihydrate, Sodium Chloride, Sodium Citrate , May Contain Hydrochloric Acid and/or Sodium Hydroxide to Adjust PH.

PRINCIPAL DISPLAY PANEL



CardinalHealth™

SGS Rosemont
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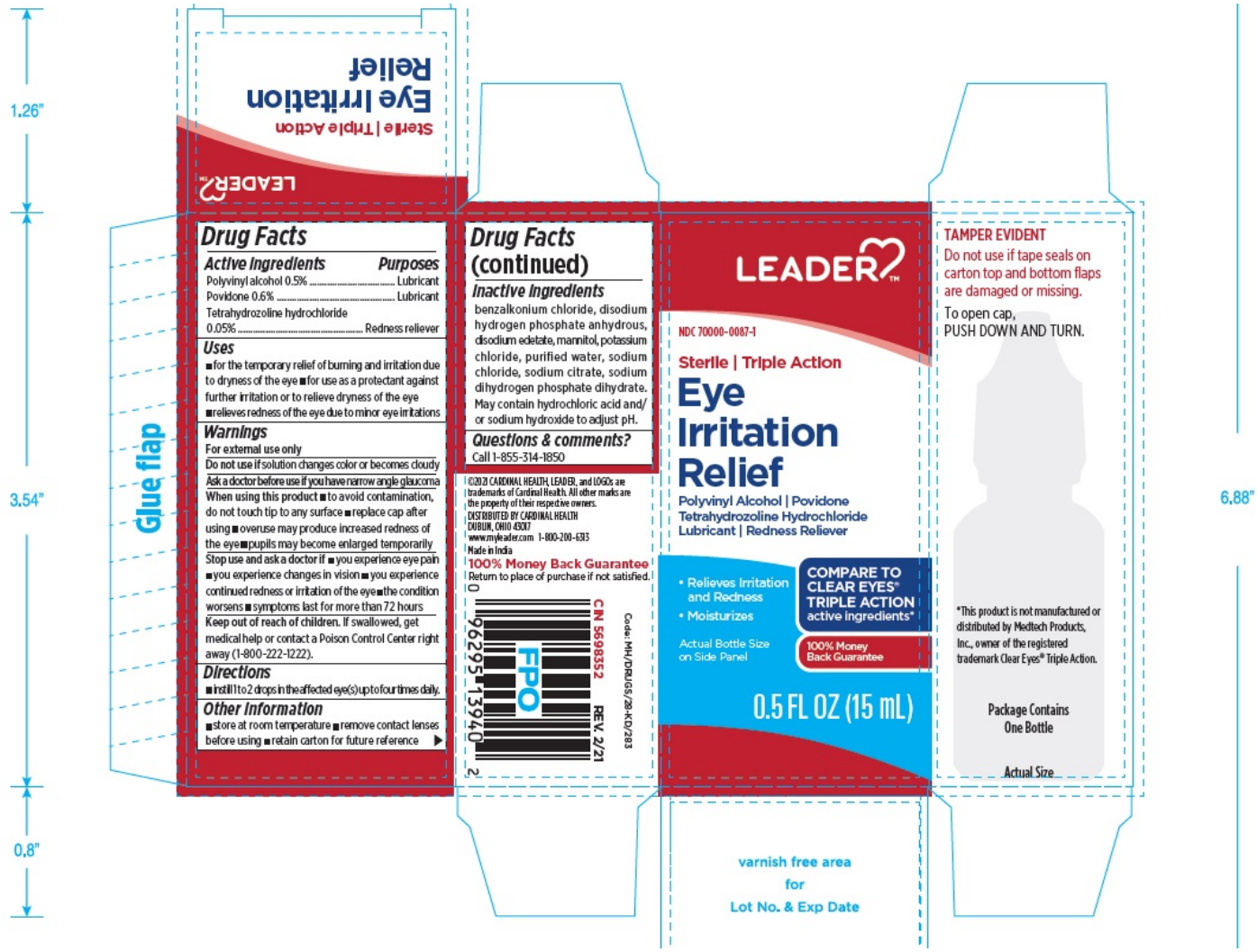
SGS Job Number:	INITIALS	DATE
6270978	AC	02.19.21

CIN Number: 5698352 **Brand:** LEADER
Component Code: 5698352-Bottle (Label)
Product Name: Triple Eye Irritation Relief 0.5oz
File Name: 6270978 CAH LDR Triple Eye Irritation Relief 0.5oz Bottle_VEL_425750212113101_5698352_V2.ai
Die Dimensions: 2.95" x 1.26"
Packaging Type: Bottle (Label)

1	2	3	4	5
PMS 200	PROCESS CYAN	PMS 661	PROCESS BLACK	VARNISH

DIELINE



EYES IRRITATION RELIEF

polyvinyl alcohol and povidone and tetrahydrozoline hydrochloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70000-0087
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990) (POLYVINYL ALCOHOL, UNSPECIFIED - UNII:532B59J990)	POLYVINYL ALCOHOL, UNSPECIFIED	5 mg in 1 mL
POVIDONE (UNII: FZ989GH94E) (POVIDONE - UNII:FZ989GH94E)	POVIDONE	6 mg in 1 mL
TETRAHYDROZOLINE HYDROCHLORIDE (UNII: 0YZT43HS7D) (TETRAHYDROZOLINE - UNII:S9U025Y077)	TETRAHYDROZOLINE HYDROCHLORIDE	0.5 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	

SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
SODIUM PHOSPHATE, MONOBASIC, DIHYDRATE (UNII: 5QWK665956)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
MANNITOL (UNII: 3OWL53L36A)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
WATER (UNII: 059QF0KO0R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0087-1	1 in 1 BOX	03/09/2021	
1		15 mL in 1 BOTTLE, DROPPER; 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	03/09/2021	

Labeler - Cardinal Health, 110 dba LEADER (063997360)

Revised: 6/2021 Cardinal Health, 110 dba LEADER