EYE DROPS - glycerin solution
Opto-Pharm Pte 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

Glycerin.....1.0%

Purpose

Lubricant

Uses

- For use as a lubricant to prevent further irritation or to relieve dryness of the eye
- 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

solution changes color or becomes cloudy

When using this product

- to avoid contamination, do not touch tip of container to any surface
- replace cap after using

Stop use and 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 or persists for more than 72 hours

Keep out of reach of children

If product is 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

Other informations

- store in the refrigerator

- do not freeze
- store in dark, cool place away from sunlight
- once open, discard container and any contents after 30 days
- use before expiration date marked on container
- prior to drop instillation, contact lenses should be removed and reinserted after 10 minutes

Inactive ingredients

boric acid, citric acid, hypromellose, N-acetyl-carnosine, potassium bicarbonate, purified benzyl alcohol, sterile water

Questions

+65-68614801

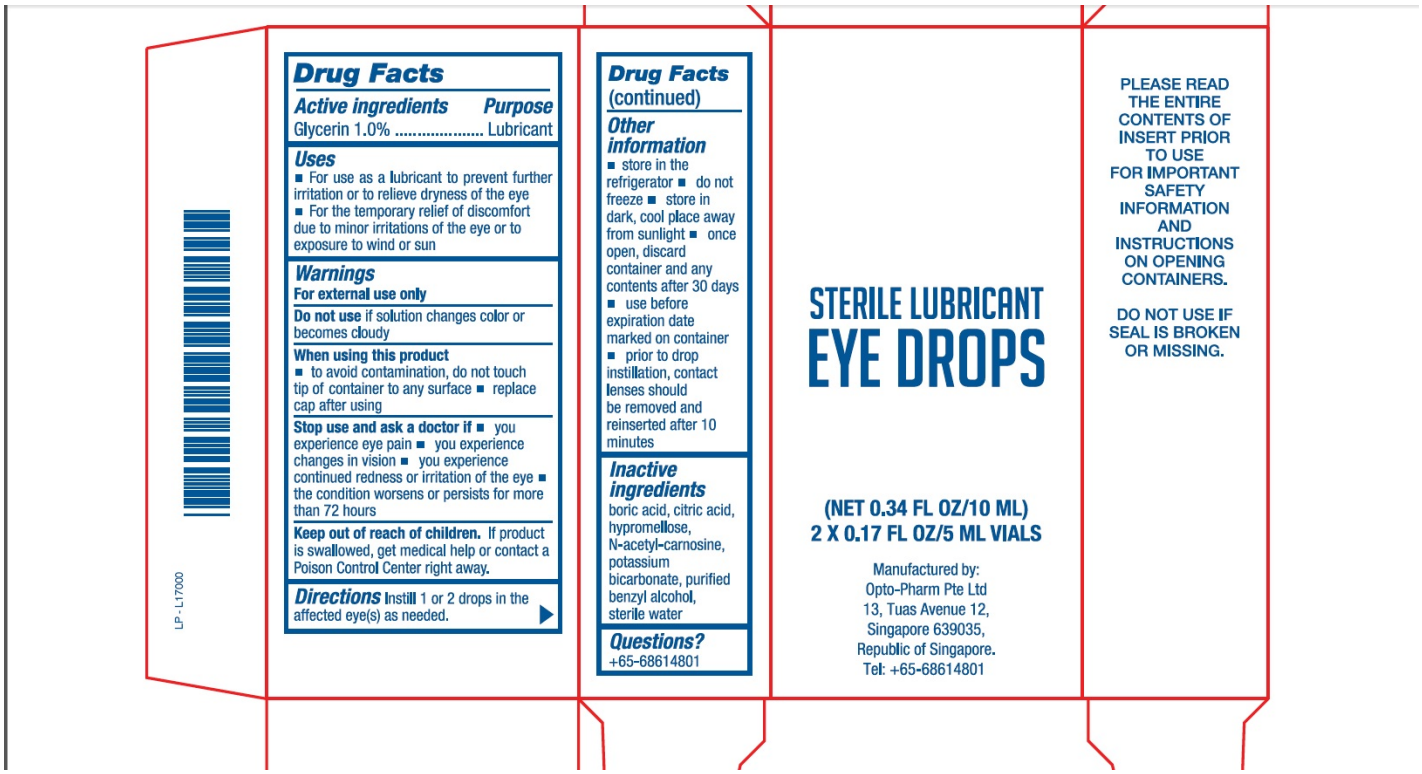
Principal Display Panel

NDC 46823-001-05

STERILE LUBRICANT EYE DROPS

2X0.17 fl oz/5 ml vials

(Net 0.34 fl oz/10 ml)



EYE DROPS

glycerin solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:46823-001

Route of Administration	OPHTHALMIC

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	1 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
BORIC ACID (UNII: R57ZHV85D4)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
N-ACETYLCARNOSINE (UNII: 0TPN86OQIF)	
POTASSIUM BICARBONATE (UNII: HM5Z15LEBN)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:46823-001-05	10 g in 1 VIAL; Type 0: Not a Combination Product	03/06/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	03/06/2017	

Labeler - Opto-Pharm Pte Ltd (595239682)

Registrant - Opto-Pharm Pte Ltd (595239682)

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