GONIOVISC OPHTHALMIC LUBRICANT- hypromellose 2910 (4000 mpa.s) solution/drops HUB Pharmaceuticals, LLC

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.

GONIOVISC Eye Lubricant Hypromellose Ophthalmic Solution, USP 2.5%, Drops (Sterile)

ACTIVE INGREDIENTS:

Active Ingredients Purpose

Hypromellose 25 mg (2.5%).....Lubricant

USES:

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

Indications & Usage:

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

WARNINGS:

- For external use only.
- Do not use if sealed bottle tip is broken or punctured.
- If solution changes color or becomes cloudy, do not use.

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 physician

If you experience eye pain, changes in vision, continued redness or irritation of the eye, or if the condition worsens or persists for more than 72 hours, discontinue use and consult a doctor.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

In case of overdose, 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 INFORMATION:

- Store at room temperature 15°-30°C (59°-86°F).
- Do not freeze.

• Keep box for complete information.

INACTIVE INGREDIENTS:

Inactive Ingredients:

- Boric Acid
- Edetate Disodium
- Hydrochloric Acid and/or Sodium Hydroxide may be added to adjust pH (6.0-7.8)
- Sodium Borate
- Water for Injection

Preservative:

• Benzalkonium Chloride Solution NF 0.02% v/v

Questions?

1-800-Eye-Drop (393-3767)

PACKAGE LABELS:

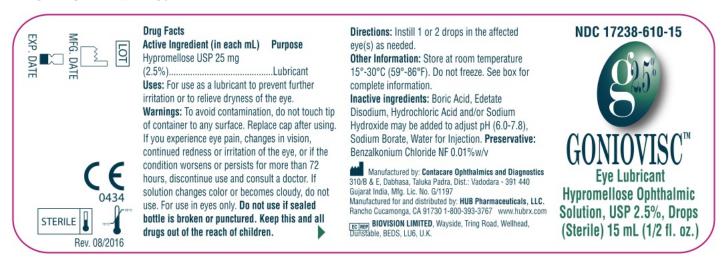


Image 1: Label for Bottle





To open bottle, wist cap clockwise

Drug Facts

Active Ingredient (in each mL)

Purpose

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..Lubricant

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Drug Facts (continued)

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Other information

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- . Keep box for complete information.

Inactive ingredients

Boric Acid, Edetate Disodium, Hydrochloric Acid and/or Sodium Hydroxide may be added to adjust pH (6.0-7.8), Sodium Borate, Water for Injection

Preservative

Benzalkonium Chloride NF 0.01%w/v

Questions? 1-800-Eye-Drop (393-3767)

NDC 17238-610-15



GONIOVISCTM

Eye Lubricant Hypromellose Ophthalmic Solution, USP 2.5%, Drops (Sterile) 15 mL (1/2 fl. oz.)

STERILE



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Manufactured by: Contacare Ophthalmics and Diagnostics 310/B & E, Dabhasa, Taluka Padra, Dist.:Vadodara - 391 440 Gujarat India, Mfg. Lic. No. G/1197

Manufactured for and distributed by: **HUB Pharmaceuticals, LLC.** Rancho Cucamonga, CA 91730 1-800-393-3767 www.hubrx.com

EC REP BIOVISION LIMITED Wayside, Tring Road, Wellhead, Dunstable, BEDS, LU6, U.K.







Image 2: Label for Box

GONIOVISC OPHTHALMIC LUBRICANT

hypromellose 2910 (4000 mpa.s) solution/ drops

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:17238-610

Route of Administration OPHTHALMIC

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
HYPROMELLOSE 2910 (4000 MPA.S) (UNII: RN3152OP35) (HYPROMELLOSE 2910 (4000 MPA.S) - UNII:RN3152OP35)	HYPROMELLOSE 2910 (4000 MPA.S)	25 mg in 1 mL		

Inactive Ingredients		
Ingredient Name	Strength	
BORIC ACID (UNII: R57ZHV85D4)		
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)		
SODIUM BORATE (UNII: 91MBZ8H3QO)		
WATER (UNII: 059QF0KO0R)		
HYDRO CHLORIC ACID (UNII: QTT17582CB)		
SO DIUM HYDRO XIDE (UNII: 55X04QC32I)		
BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7)		

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:17238-610- 15	1 in 1 BOX	11/10/2011		
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	11/10/2011	

Labeler - HUB Pharmaceuticals, LLC (611747945)

Establishment				
Name	Address	ID/FEI	Business Operations	
Contacare Ophthalmics & Diagnostics		915821765	manufacture(17238-610)	

Revised: 12/2017 HUB Pharmaceuticals, LLC