

**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:

EXP. DATE **MFG. DATE** **LOT**

Drug Facts
Active Ingredient (in each mL) Purpose
 Hypromellose USP 25 mg (2.5%).....Lubricant
Uses: For use as a lubricant to prevent further irritation or to relieve dryness of the eye.
Warnings: To avoid contamination, do not touch tip of container to any surface. Replace cap after using. 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 solution changes color or becomes cloudy, do not use. For use in eyes only. **Do not use if sealed bottle is broken or punctured. Keep this and all drugs out of the reach of children.**

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. See 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

CE
0434
STERILE
Rev. 08/2016

NDC 17238-610-15

g.v.5
GONIOVISC™
 Eye Lubricant
 Hypromellose Ophthalmic
 Solution, USP 2.5%, Drops
 (Sterile) 15 mL (1/2 fl. oz.)

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
BIOVISION LIMITED, Wayside, Tring Road, Welhead,
 Dunstable, BEDS, LU6, U.K.

Image 1: Label for Bottle

Remove cap.
to puncture sterile seal.



To open bottle,
twist cap clockwise

Drug Facts	Drug Facts (continued)		
<p>Active Ingredient (in each mL) Hypromellose USP 25 mg (2.5%).....Lubricant</p> <p>Purpose Lubricant</p> <p>Uses</p> <ul style="list-style-type: none"> For use as a lubricant to prevent further irritation or to relieve dryness of the eye. For use in the eyes only. <p>Warnings</p> <p>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.</p> <p>When using this product</p> <ul style="list-style-type: none"> To avoid contamination, do not touch tip of container to any surface. Replace cap after using. <p>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 ▶</p>	<p>use and consult a doctor.</p> <p>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.</p> <p>Directions Instill 1 or 2 drops in the affected eye(s) as needed.</p> <p>Other information</p> <ul style="list-style-type: none"> Store at room temperature 15°-30°C (59°-86°F). • Do not freeze. Keep box for complete information. <p>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</p> <p>Preservative Benzalkonium Chloride NF 0.01%w/v</p> <p>Questions? 1-800-Eye-Drop (393-3767)</p>	<p>NDC 17238-610-15</p>  <p>GONIOVISC™ Eye Lubricant Hypromellose Ophthalmic Solution, USP 2.5%, Drops (Sterile) 15 mL (1/2 fl. oz.)</p> <p>STERILE </p>	 <p>GONIOVISC™ Eye Lubricant Hypromellose Ophthalmic Solution, USP 2.5%, Drops (Sterile) 15 mL (1/2 fl. oz.)</p> <p><small>Manufactured by: Contacare Ophthalmics and Diagnostics 310/B & E, Dabhaha, Taluka Padra, Dist.:Vadodara - 391 440 Gujarat India, Mfg. Lic. No. G/1197</small></p> <p><small>Manufactured for and distributed by: HUB Pharmaceuticals, LLC. Rancho Cucamonga, CA 91730 1-800-393-3767 www.hubrx.com</small></p> <p><small>EC REP BIOVISION LIMITED Wayside, Tring Road, Welstead, Dunstable, BEDS, LU6, U.K.</small></p>  <p>3 17238 61015 5</p>

Rev. 08/2016 

LOT 

MFG. DATE 

EXP. DATE 

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:17238-6 10
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 DISODIUM (UNII: 7FLD91C86K)	
SODIUM BORATE (UNII: 91MBZ8H3QO)	
WATER (UNII: 059QF0K00R)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
BENZALKONIUM CHLORIDE (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