BION TEARS- dextran, hypromellose solution/ drops
Alcon Laboratories, Inc.

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.

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Drug Facts

<table>
<thead>
<tr>
<th>Active Ingredients</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dextran 70 0.1%</td>
<td>Lubricant</td>
</tr>
<tr>
<td>Hypermellose 2910 0.3%</td>
<td>Lubricant</td>
</tr>
</tbody>
</table>

Uses
- For use as a protectant against further irritation or to relieve dryness of the eye.

Warnings
For external use only

Do not use
- if this solution changes color or becomes cloudy.
- if you are sensitive to any ingredient in this product.

When using this product
- To avoid contamination, do not touch tip of container to any surface.
- Do not touch unit-dose tip to eye.
- Do not reuse. Once opened, discard.

Stop use and ask a doctor if you experience
- eye pain
- changes in vision
- continued redness
- irritation of the eye
- symptoms worsening or persisting 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
- Instill 1 or 2 drops in the affected eye(s) as needed.

Other Information
Store at room temperature.

Inactive Ingredients
Calcium chloride, magnesium chloride, potassium chloride, purified water, sodium bicarbonate, sodium chloride, zinc chloride, hydrochloric acid and/or sodium hydroxide and/or carbon dioxide to adjust pH.

**Questions?**
In the U.S. call 1-800-757-9195  
www.tearsnaturale.com  
MedInfo@AlconLabs.com

**PRINCIPAL DISPLAY PANEL**
Severe Dry Eye  
Preservative-Free  
**BION® TEARS**  
LUBRICANT EYE DROPS  
28 Single-Use Vials  
0.4 ml (0.015 FL OZ) Each  
STERILE  
Alcon®  
**DIRECTIONS (HOW TO USE)**
Make sure container is intact before use.  
To open, COMPLETELY TWIST OFF TAB.  
Do not pull off.  
Instill 1 or 2 drops in the affected eye(s) as needed.  
Throw away container.  
Do not reuse.  
Once opened, discard.  
All four containers within a pouch must be used within four days of opening the pouch.  

**Tamper Evident:** Containers are sealed in a protective foil pouch. Use only if foil pouch is undamaged at time of purchase.  

BION® TEARS Lubricant Eye Drops is an advanced tear substitute especially formulated and packaged for persistent dry eye conditions requiring frequent therapy.  

**MONEY BACK GUARANTEED**
To fully assess comfort, a 3 to 4-week trial of BION® TEARS is recommended when switching from another brand of lubricant eye drops. If, however, you are not satisfied with the comfort BION® TEARS provides, we ask that you send the unused portion of the product and the sales receipt, with a brief description of why your were dissatisfied, to QA/Consumer Affairs, Alcon laboratories, Fort Worth, TX 76134-2099. You will receive a full refund within 6 to 8 weeks. U.S. Patent no. 5,403,598
BION TEARS
dextran, hypromellose solution/ drops

Product Information

Product Type: HUMAN OTC DRUG
Route of Administration: OPTHALMIC

Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dextran 70 (UNII: 7SA290 YK68) (Dextran 70 - UNII:7SA290 YK68)</td>
<td>Dextran 70</td>
<td>1 mg in 1 mL</td>
</tr>
<tr>
<td>Hypromellose 2910 (4000 Mpa.s) (UNIERN3152OP35) (Hypermellose 2910 (4000 Mpa.s) - UNIERN3152OP35)</td>
<td>Hypermellose 2910 (4000 Mpa.s)</td>
<td>3 mg in 1 mL</td>
</tr>
</tbody>
</table>

Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium Chloride (UNII: M4I0D6VV5M)</td>
<td></td>
</tr>
</tbody>
</table>
Magnesium Chloride (UNII: 02F3473H9O)
Potassium Chloride (UNII: 660YQ98II0)
Water (UNII: 059QF0KO0R)
Sodium Bicarbonate (UNII: 8MDF5V39QO)
Sodium Chloride (UNII: 451W47IQ8X)
Zinc Chloride (UNII: 86Q357L16B)
Hydrochloric Acid (UNII: QTT17582CB)
Sodium Hydroxide (UNII: 55X04QC32I)
Carbon Dioxide (UNII: 142M471B3J)

Packaging

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>NDC:0065-0419-28</td>
<td>28 in 1 CARTON</td>
<td>10/20/2000</td>
<td>12/21/2017</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td>0.4 mL in 1 VIAL; Type 0: Not a Combination Product</td>
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<tr>
<td>2</td>
<td>NDC:0065-0419-18</td>
<td>28 in 1 CARTON</td>
<td>10/20/2000</td>
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<td>0.4 mL in 1 VIAL; Type 0: Not a Combination Product</td>
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Marketing Information

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<tr>
<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
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<tbody>
<tr>
<td>OTC monograph final</td>
<td>part349</td>
<td>10/19/1992</td>
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Labeler - Alcon Laboratories, Inc. (008018525)

Establishment

<table>
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<tr>
<th>Name</th>
<th>Address</th>
<th>ID/FEI</th>
<th>Business Operations</th>
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<tbody>
<tr>
<td>Kaysersberg Pharmaceuticals</td>
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<td>267486052</td>
<td>manufacture(0065-0419)</td>
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Revised: 11/2019

Alcon Laboratories, Inc.