LUBRICANT EYE DROPS- polyethylene glycol 400 and propylene glycol solution/ drops

Chain Drug Consortium

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

Active ingredients
Polyethylene Glycol 400 0.4%
Propylene Glycol 0.3%

Purpose
Lubricant

Uses
For the temporary relief of burning and irritation due to dryness of the eye.

Warnings
For external use only.

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

When using this product
- do not touch tip of container to any surface to avoid contamination
- replace cap after each use

Stop use and ask a doctor if
- you feel eye pain
- changes in vision occur
- redness or irritation of the eye(s) gets worse, persists or lasts 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 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

Inactive ingredients
Purified Water, Boric Acid, Hypromellose, Sodium Chloride, Potassium Chloride, Zinc Chloride, Calcium Chloride Dihydrate, Magnesium Chloride Hexahydrate. May contain Hydrochloric Acid and/or Sodium Hydroxide to adjust pH;

**Preservative**

Benzalkonium Chloride.

**Questions or comments?**

1-800-932-5676

Principal Display Panel Text for Container Label:

68016-404-00

Premier Value® Logo

Lubricant Eye Drops

PEG-PHEN LUBRICANT EYE DROPS

- Long lasting
- Soothing comfort dry eye therapy

15 mL (0.5 FL OZ) STERILE

Principal Display Panel Text for Carton Label:

68016-404-00

*COMPARE TO THE ACTIVE INGREDIENT IN SYSTANE®*
Premier Value Logo
Lubricant
Eye Drops
PEG-PHEN
LUBRICANT
EYE DROPS
- Long lasting
- Soothing comfort

dry eye therapy
15 mL (0.5 FL OZ)
STERILE PV Brand Logo
# LUBRICANT EYE DROPS
polyethylene glycol 400 and propylene glycol solution/ drops

## Product Information

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Item Code (Source)</th>
<th>NDC:68016-404</th>
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</thead>
<tbody>
<tr>
<td>HUMAN OTC DRUG</td>
<td></td>
<td></td>
</tr>
<tr>
<td>OPHTHALMIC</td>
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</tbody>
</table>

## Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polyethylene Glycol 400</td>
<td>Polyethylene Glycol 400</td>
<td>4 mg in 1 mL</td>
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### Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Water</strong> (UNII: 059QF0KO0R)</td>
<td>3 mg in 1 mL</td>
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<tr>
<td>Boric Acid (UNII: R57ZHV85D4)</td>
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</tr>
<tr>
<td>Hypromelloses (UNII: 3NXW29V3WO)</td>
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<tr>
<td>Sodium Chloride (UNII: 451W47IQ8X)</td>
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</tr>
<tr>
<td>Potassium Chloride (UNII: 660YQ98110)</td>
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<tr>
<td>Zinc Chloride (UNII: 86Q357L16B)</td>
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<tr>
<td>Calcium Chloride (UNII: M4ID6DY5M)</td>
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</tr>
<tr>
<td>Magnesium Chloride (UNII: 02F3473H9O)</td>
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<tr>
<td>Hydrochloric Acid (UNII: QTT17582CB)</td>
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</tr>
<tr>
<td>Sodium Hydroxide (UNII: 55X04QC32I)</td>
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</tr>
<tr>
<td>Benzalkonium Chloride (UNII: F5UM2KM3W7)</td>
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### 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:68016-404-00</td>
<td>1 in 1 CARTON</td>
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</tr>
<tr>
<td>1</td>
<td></td>
<td>15 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product</td>
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</table>

### Marketing Information

<table>
<thead>
<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>01/10/2014</td>
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### Labeler
- Chain Drug Consortium (101668460)

### Registrant
- Akorn, Inc. (062649876)

### Establishment

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>ID/FEI</th>
<th>Business Operations</th>
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<tbody>
<tr>
<td>Akorn, Inc</td>
<td>603980319</td>
<td>MANUFACTURE(68016-404), ANALYSIS(68016-404), STERILIZE(68016-404), PACK(68016-404), LABEL(68016-404)</td>
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</tbody>
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Revised: 10/2015