SYSTANE - hypromellose gel  
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 ingredient</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypromellose (0.3%)</td>
<td>Lubricant</td>
</tr>
</tbody>
</table>

Uses
- for the temporary relief of discomfort due to minor irritations of the eye or to exposure to wind or sun
- for use as a protectant against further irritation or to relieve dryness of the eye

Warnings
For external use only

Do not use
- if gel 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
- replace cap after each use

Stop use and ask a doctor if you experience any of the following:
- eye pain
- changes in vision
- continued redness or irritation of the eye
- condition worsens or persists 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
put 1 or 2 drops in the affected eye(s) as needed

Other information
store between 15° – 30°C (59° – 86°F)

Inactive ingredients
carbopol 980, phosphonic acid, purified water, sodium perborate and sorbitol. May contain sodium
hydroxide to adjust pH.

**Questions?**
In the U.S. call toll-free
1-866-393-6336
alcon.medinfo@alcon.com

**TAMPER EVIDENT:** For your protection, use only if pull tab is intact at time of purchase.

**PRINCIPAL DISPLAY PANEL**
NDC 0065047401

**Systane® GEL**
LUBRICANT EYE GEL

**NIGHTTIME PROTECTION**
Delivers long-lasting relief of dry eye symptoms

**Alcon®**

STERILE
10g (0.34 FL OZ)
## Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypromellose 2910 (4000 Mpa.s) (UNII: RN3152OP35)</td>
<td>Hypromellose 2910 (4000 Mpa.s)</td>
<td>3 mg in 1 g</td>
</tr>
</tbody>
</table>

## Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carbomer Homopolymer Type C (allyl Pentaerythritol Crosslinked) (UNII: 4Q93RCW27E)</td>
<td></td>
</tr>
<tr>
<td>Phosphonic Acid (UNII: 35V6A8JW8E)</td>
<td></td>
</tr>
<tr>
<td>Water (UNII: 059QF0KOOR)</td>
<td></td>
</tr>
<tr>
<td>Sodium Perborate (UNII: Y52BK1W96C)</td>
<td></td>
</tr>
<tr>
<td>Sorbitol (UNII: 506T60A25R)</td>
<td></td>
</tr>
<tr>
<td>Sodium Hydroxide (UNII: 55X04Q3C2I)</td>
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</tr>
</tbody>
</table>

## Packaging

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>NDC:0065-0474-01</td>
<td>1 in 1 CARTON</td>
<td>12/15/2012</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td></td>
<td>10 g in 1 TUBE; Type 0: Not a Combination Product</td>
<td>12/15/2012</td>
<td>12/31/2018</td>
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<tr>
<td>2</td>
<td>NDC:0065-0474-02</td>
<td>1 in 1 CARTON</td>
<td>12/15/2012</td>
<td></td>
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<tr>
<td>2</td>
<td></td>
<td>3.5 g in 1 TUBE; Type 0: Not a Combination Product</td>
<td>12/15/2012</td>
<td>12/31/2018</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>12/15/2012</td>
<td></td>
</tr>
</tbody>
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## Labeler

- Alcon Laboratories, Inc. (008018525)

## Establishment

### Akorn AG
- Name: Akorn AG
- Address: 482198285
- ID/FEI: manufacture(0065-0474), label(0065-0474), pack(0065-0474)

### Excelvision
- Name: Excelvision
- Address: 274234566
- ID/FEI: manufacture(0065-0474), label(0065-0474), pack(0065-0474)

### SERVIPACK
- Name: SERVIPACK
- Address: 571772875
- ID/FEI: label(0065-0474), pack(0065-0474)