ARTIFICIAL TEARS- polyvinyl alcohol solution/ drops
Cardinal Health

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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Artificial Tears Solution Drug Facts

Active ingredient
Polyvinyl Alcohol 1.4%

Purpose
Lubricant

Uses
• temporary relieve of burning and irritation due to dryness of the eye

Warnings
• Do not use if solution changes color or becomes cloudy

When using this product
• do not touch tip of container to any surface to avoid contamination

Stop use and ask a doctor if
• you experience 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
• instill 1 to 2 drops in the affected eye(s) as needed

Other information
• store at 15° - 30°C (59° - 86°F)
• keep tightly closed
• replace cap after use

Inactive ingredients
dibasic sodium phosphate, edetate disodium, monobasic sodium phosphate,
purified water, sodium chloride. Phosphoric acid and/or sodium hydroxide may be added to adjust pH.
PRESERVATIVE ADDED: benzalkonium chloride 0.01%

Questions?
Serious side effects associated with use of this product may be reported to 1800-323-0000
DO NOT USE IF IMPRINTED "Protective Seal" WITH YELLOW IS NOT INTACT.

Package/Label Principal Display Panel

NDC 37205-137-05
LEADER®
Compare to Liquifilm Tears®* active ingredient*
Artificial Tears Solution
Polyvinyl Alcohol 1.4%
Lubricant Eye Drops
(Sterile)
FOR USE IN THE EYES ONLY
SATISFACTION GUARANTEED 1/2 FL. OZ. (15 mL)

ARTIFICIAL TEARS
polyvinyl alcohol solution/ drops

Product Information

| Product Type       | HUMAN OTC DRUG | Item Code (Source) | NDC:37205-137 |
### Route of Administration
OPHTHALMIC

### Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>POLYVINYL ALCOHOL (UNII: 532B59J990) (POLYVINYL ALCOHOL - UNII:532B59J990)</td>
<td>POLYVINYL ALCOHOL</td>
<td>14 mg in 1 mL</td>
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</tbody>
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### Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)</td>
<td></td>
</tr>
<tr>
<td>EDETATE DISODIUM (UNII: 7FLD91C86K)</td>
<td></td>
</tr>
<tr>
<td>SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JB2SW)</td>
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</tr>
<tr>
<td>SODIUM CHLORIDE (UNII: 451W47IQ8X)</td>
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</tr>
<tr>
<td>WATER (UNII: 059QF0KO0R)</td>
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<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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<tbody>
<tr>
<td>1</td>
<td>NDC:37205-137-05</td>
<td>15 mL in 1 BOTTLE</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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<tr>
<td>OTC monograph final</td>
<td>part349</td>
<td>11/15/2011</td>
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### Labeler
Cardinal Health (097537435)

### Registrant
Bausch & Lomb Incorporated (196603781)

### Establishment

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<tr>
<th>Name</th>
<th>Address</th>
<th>ID/FEI</th>
<th>Business Operations</th>
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<tr>
<td>Bausch &amp; Lomb Incorporated</td>
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<td>807927397</td>
<td>MANUFACTURE</td>
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Revised: 11/2011