NAPHAZOLINE HCl AND PHENIRAMINE MALEATE - naphazoline hydrochloride, pheniramine maleate solution/drops
Altaire Pharmaceuticals Inc.
---------
Naphazoline HCl 0.027% & Pheniramine Maleate 0.315% Ophthalmic Solution, USP

Active Ingredients
Naphazoline Hydrochloride (0.027%)
Pheniramine Maleate (0.315%)

Purpose
Redness Reliever
Antihistamine

Uses: temporarily relieves itching and redness caused by pollen, ragweed, grass, animal hair and dander.

Warnings: 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 physician. Do not use in children under 6 years of age unless directed by a physician. If this solution changes color or becomes cloudy, do not use. Overuse of this product may produce increased redness of the eye.

If you are sensitive to any ingredient in this product, do not use. To avoid contamination, do not touch tip of container to any surface. Replace cap after using.

Do not use if imprinted seal on cap is torn, broken or missing, or if imprinted seals on top and bottom flaps are not intact and completely legible.

Ask a doctor before use if
- heart disease
- high blood pressure
- trouble urinating due to enlarged prostate gland
- narrow angle glaucoma

Remove contact lenses before using.

Stop use and ask a doctor if you experience: eye pain, changes in vision, redness or irritation of the eye that worsens or persists for more than 72 hours. Overuse of this product may produce increased redness of the eye. Pupils may become enlarged temporarily. You may experience a brief tingling sensation after putting drops in eyes.

Keep out of reach of children.

In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately. Accidental oral ingestion in infants and children may lead to coma and marked reduction in body temperature.

Directions:
Adults and children 6 years of age and older: instill 1 or 2 drops in affected eye(s) up to 4 times daily.
Children under 6 years: ask a doctor.

Store at room temperature 20 degrees - 25 degrees C (68 degrees - 77 degrees F).

Protect from light.

Use before expiration date marked on the carton or bottle.
Available in 15mL NDC 59390-177-13 and 30 mL NDC 59390-177-18

Inactive ingredients
benzalkonium chloride 0.01%, boric acid, edetate disodium 0.1%, hypromellose, purified water, sodium borate, and sodium chloride.

Questions or comments
Call (631) 722-5988 9am - 5pm EST Monday - Friday

Manufactured by:
Altaire Pharmaceuticals, Inc.
Aquebogue, N.Y. 11931

ALTAIRE Pharmaceuticals, Inc.
Aquebogue, N.Y. 11931

Naphazoline HCl 0.027%
and
Pheniramine Maleate 0.315%

Ophthalmic Solution, USP
Eye Allergy Relief
With Antihistamine To Relieve Itching

Itching and Redness Reliever
Eye Drops

0.5 Fl. OZ. (15mL)
NAPHAZOLINE HCI AND PHENIRAMINE MALEATE
naphazoline hydrochloride, pheniramine maleate solution/drops

Product Information

<table>
<thead>
<tr>
<th>Product Type</th>
<th>HUMAN OTC DRUG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Route of Administration</td>
<td>OPHTHALMIC</td>
</tr>
<tr>
<td>Item Code (Source)</td>
<td>NDC:59390-177</td>
</tr>
</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>NAPHAZOLINE HYDROCHLORIDE (UNII: MZ1131787D) (NAPHAZOLINE - UNII:H231GF11BV)</td>
<td>NAPHAZOLINE HYDROCHLORIDE</td>
<td>0.027 mL in 100 mL</td>
</tr>
<tr>
<td>PHENIRAMINE MALEATE (UNII: NYW905655B) (PHENIRAMINE - UNII:134FM9ZZ6M)</td>
<td>PHENIRAMINE MALEATE</td>
<td>0.315 mL in 100 mL</td>
</tr>
</tbody>
</table>

Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)</td>
<td></td>
</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:59390-177-13</td>
<td>15 mL in 1 BOTTLE, DROPPER</td>
<td></td>
<td></td>
</tr>
</tbody>
</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>
</tr>
</thead>
<tbody>
<tr>
<td>ANDA</td>
<td>ANDA078208</td>
<td>10/06/2010</td>
<td></td>
</tr>
</tbody>
</table>

Labeler - Altaire Pharmaceuticals Inc. (786790378)

Establishment

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>ID/FEI</th>
<th>Business Operations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Altaire Pharmaceuticals Inc.</td>
<td></td>
<td>786790378</td>
<td>manufacture</td>
</tr>
</tbody>
</table>

Revised: 10/2010