OXYMETAZOLINE HCL- oxymetazoline hydrochloride spray
Perrigo New York 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.

----------

Perrigo Oxymetazoline HCl 0.05% Drug Facts

Active ingredient
Oxymetazoline hydrochloride 0.05%

Purpose
Nasal decongestant

Uses

• temporarily relieves nasal congestion due to:
  • common cold
  • hay fever
  • upper respiratory allergies
  • temporarily relieves sinus congestion and pressure
  • shrinks swollen nasal membranes so you can breathe more freely

Warnings

Ask a doctor before use if you have

• heart disease
• high blood pressure
• diabetes
• thyroid disease
• trouble urinating due to an enlarged prostate gland

When using this product

• do not use more than directed
• do not use for more than 3 days. Use only as directed. Frequent or prolonged use may cause nasal congestion to recur or worsen.
• temporary discomfort such as burning, stinging, sneezing or an increase in nasal discharge may occur
• use of this container by more than one person may spread infection

Stop use and ask a doctor if
symptoms persist

If pregnant or breast-feeding,
ask a health professional before use.

**Keep out of reach of children.**
If swallowed, get medical help or contact a Poison Control Center right away (1-800-222-1222).

**Directions**

- adults and children 6 to under 12 years of age (with adult supervision): 2 or 3 sprays in each nostril not more often than every 10 to 12 hours. Do not exceed 2 doses in any 24-hour period.
- children under 6 years of age: ask a doctor

To Use: Push firmly down on cap and turn counter clockwise. To spray, squeeze bottle quickly and firmly. Do not tilt head backward while spraying. Wipe nozzle clean after use. Secure cap after use.

**Other information**

- store at 20-25°C (68-77°F)
- retain carton for future reference on full labeling

**Inactive ingredients**
benzalkonium chloride solution, benzyl alcohol, dibasic sodium phosphate, edetate disodium, monobasic sodium phosphate, polyethylene glycol, povidone, propylene glycol, purified water

**Questions or comments?**
1-800-719-9260

**Principal Display Panel**
Compare to Afrin® active ingredient
Oxymetazoline HCl 0.05%
Nasal Decongestant
Fast, Powerful Congestion Relief
For Colds & Allergies
Maximum Strength
12 Hour Relief
Spray Mist
1 FL OZ (30 mL)
OXYMETAZOLINE HCL
oxymetazoline hydrochloride spray

Product Information

<table>
<thead>
<tr>
<th>Product Type</th>
<th>HUMAN OTC DRUG</th>
<th>Item Code (Source)</th>
<th>NDC: 45802-410</th>
</tr>
</thead>
<tbody>
<tr>
<td>Route of Administration</td>
<td>NASAL</td>
<td></td>
<td></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>
</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>
<tr>
<td>BENZYL ALCOHOL (UNII: LKG8494WBH)</td>
<td></td>
</tr>
<tr>
<td>SODIUM PHOSPHATE, DIBASIC, UNSPECIFIED FORM (UNII: GR686LBA74)</td>
<td></td>
</tr>
<tr>
<td>EDETATE DISODIUM (UNII: 7FLD91C86K)</td>
<td></td>
</tr>
<tr>
<td>SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM (UNII: 3980J82SW)</td>
<td></td>
</tr>
<tr>
<td>POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)</td>
<td></td>
</tr>
<tr>
<td>POVIDONE, UNSPECIFIED (UNII: FZ989GH4E)</td>
<td></td>
</tr>
<tr>
<td>PROPYLENE GLYCOL (UNII: 6DC9Q167V3)</td>
<td></td>
</tr>
<tr>
<td>WATER (UNII: 059QF0KO0R)</td>
<td></td>
</tr>
</tbody>
</table>

### Product Characteristics

#### Color
WHITE (Translucent)

#### Shape

#### Size

#### Flavor

#### Imprint Code

### 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:45802-410-59</td>
<td>1 in 1 CARTON</td>
<td>12/05/2005</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td></td>
<td>30 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product</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>OTC monograph final</td>
<td>part341</td>
<td>12/05/2005</td>
<td></td>
</tr>
</tbody>
</table>

### Labeler
- Perrigo New York Inc (078846912)

Revised: 12/2019