NASAL- oxymetazoline hydrochloride spray
Major Pharmaceuticals

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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MAJOR®
Soothing - 12 Hour
NASAL DECONGESTANT
Spray

Drug Facts

Active ingredient
Oxymetazoline hydrochloride 0.05%

Purpose
Nasal decongestant

Uses
• for the temporary relief of nasal congestion due to the common cold, hay fever or other upper respiratory allergies
• shrinks swollen membranes so you can breathe more freely

Warnings
Ask a doctor before use if you have
• heart disease
• high blood pressure
• thyroid disease
• diabetes
• trouble urinating due to enlarged prostate gland

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

Stop use and ask 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.

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 within any 24-hour period
• children under 6 years of age: consult a doctor

To spray, squeeze bottle quickly and firmly. Do not tilt head backward while spraying. Wipe nozzle clean after use

Other information
• store between 20° to 25° C (68° to 77° F)

Inactive ingredients
benzalkonium chloride, benzyl alcohol, dibasic sodium phosphate, edetate disodium, hydrochloric acid, monobasic sodium phosphate, polyethylene glycol 1450, povidone, propylene glycol, purified water

Questions?
To Report Adverse Drug Event Call: (800) 616-2471

PRINCIPAL DISPLAY PANEL - 15 mL Carton
NDC 0904-5711-35
MAJOR®
Soothing - 12 Hour
NASAL
DECONGESTANT
Spray
REGULAR
oxymetazoline hydrochloride 0.05%
RELIEVES CONGESTION FAST
Compare to active ingredient of Afrin®
1/2 FL.OZ.
(15 mL)
**NASAL oxymetazoline hydrochloride spray**

<table>
<thead>
<tr>
<th>Product Information</th>
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</thead>
<tbody>
<tr>
<td><strong>Product Type</strong></td>
<td>HUMAN OTC DRUG</td>
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<tr>
<td><strong>Route of Administration</strong></td>
<td>NASAL</td>
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<tr>
<td>Active Ingredient/Active Moiety</td>
<td>Ingredient Name</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>----------------</td>
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<tr>
<td>Oxymetazoline Hydrochloride</td>
<td><strong>Oxymetazoline Hydrochloride</strong> (UNII: K89MJ0S5VY) (Oxymetazoline - UNII:8VLN5B44ZY)</td>
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### Inactive Ingredients

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<tr>
<th>Ingredient Name</th>
<th>Strength</th>
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<tr>
<td>Water</td>
<td><strong>Water</strong> (UNII: 059QF0KO0R)</td>
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<tr>
<td>Benzalkonium Chloride</td>
<td><strong>Benzalkonium Chloride</strong> (UNII: F5UM2KM3W7)</td>
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<tr>
<td>Edetate Disodium</td>
<td><strong>Edetate Disodium</strong> (UNII: 7FLD91C86K)</td>
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<tr>
<td>Propylene Glycol</td>
<td><strong>Propylene Glycol</strong> (UNII: 6DC9Q167V3)</td>
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<tr>
<td>Benzy1 Alcohol</td>
<td><strong>Benzy1 Alcohol</strong> (UNII: LKG8494WBH)</td>
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<tr>
<td>Sodium Phosphate, Dibasic</td>
<td><strong>Sodium Phosphate, Dibasic</strong> (UNII: GR686LBA74)</td>
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<tr>
<td>Sodium Phosphate, Monobasic</td>
<td><strong>Sodium Phosphate, Monobasic</strong> (UNII: 39G0JH25W)</td>
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<tr>
<td>Povidone</td>
<td><strong>Povidone</strong> (UNII: FZ989GHB4E)</td>
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<tr>
<td>Hydrochloric Acid</td>
<td><strong>Hydrochloric Acid</strong> (UNII: QTT17582CB)</td>
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<tr>
<td>Polyethylene Glycol 1450</td>
<td><strong>Polyethylene Glycol 1450</strong> (UNII: OJ4ZS32L4)</td>
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### Packaging

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<th>Package Description</th>
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<td>30 mL in 1 BOTTLE, SPRAY</td>
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<td>2</td>
<td>NDC:0904-5711-30</td>
<td>15 mL in 1 BOTTLE, SPRAY</td>
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### Marketing Information

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<td>OTC MONOGRAPH FINAL</td>
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<td>03/17/2009</td>
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**Labeler** - Major Pharmaceuticals (191427277)

Revised: 2/2011