PSEUDOEPHEDRINE HYDROCHLORIDE - pseudoephedrine hydrochloride tablet, film coated
Ohm Laboratories Inc.

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Pseudoephedrine hydrochloride

Drug Facts

Active ingredient (in each tablet)
Pseudoephedrine HCl, USP 120 mg

Purpose
Nasal decongestant

Uses
- temporarily relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies
- temporarily relieves sinus congestion and pressure

Warnings
Do not use if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

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

When using this product do not exceed recommended dosage

Stop use and ask a doctor if
- nervousness, dizziness, or sleeplessness occur
- symptoms do not improve within 7 days or occur with a fever

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

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

Directions

adults and children 12 years and over
- take 1 tablet every 12 hours
- do not take more than 2 tablets in 24 hours
children under 12 years do not use this product in children under 12 years of age

Other information
- store at 59° to 77° F in a dry place. Protect from light
- TAMPER EVIDENT: DO NOT USE IF BLISTER UNITS ARE TORN, BROKEN OR SHOW ANY SIGNS OF TAMPERING.

Inactive ingredients
- castor oil, colloidal silicon dioxide, hypromellose, microcrystalline cellulose, magnesium stearate, titanium dioxide

Questions?
call 1-800-406-7984

Distributed by:
Ohm Laboratories Inc.
New Brunswick, NJ 08901

PRINCIPAL DISPLAY PANEL - 120 mg Tablet Blister Pack Carton
†Compare To the active ingredient of Sudafed® 12 Hour.
NDC 51660-204-69
ohm®
NON-DROWSY
Pseudoephedrine Hydrochloride 120 mg
12 Hour Extended-Release Tablets, USP
Long-Acting Nasal Decongestant
- SINUS PRESSURE + CONGESTION
- MAXIMUM STRENGTH

10 Coated Capsule-Shaped Tablets 120 mg Each
**PSEUDOEPHEDRINE HYDROCHLORIDE**
pseudoephedrine hydrochloride tablet, film coated

### Product Information
- **Product Type**: HUMAN OTC DRUG
- **Route of Administration**: ORAL
- **Item Code (Source)**: NDC:51660-204

### Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F) PSEUDOEPHEDRINE HYDROCHLORIDE</td>
<td></td>
<td>120 mg</td>
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### Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>CASTOR OIL (UNII: D5340Y2I9G)</td>
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</tr>
<tr>
<td>SILICONE DIOXIDE (UNII: ETJ7Z6XBU4)</td>
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</tr>
<tr>
<td>HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)</td>
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<tr>
<td>MICROCRYSTALLINE CELLULOSE (UNII: QPIR32D61U)</td>
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<tr>
<td>MAGNESIUM STEARATE (UNII: 7097M65I30)</td>
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<tr>
<td>TITANIUM DIOXIDE (UNII: 15FIX9V2JP)</td>
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### Product Characteristics
- **Color**: white
- **Shape**: CAPSULE
- **Size**: 18mm
- **Score**: no score
- **Imprint Code**: 204

### 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:51660-204-69</td>
<td>10 in 1 BLISTER PACK; Type 0: Not a Combination Product</td>
<td>04/28/2006</td>
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<td>2</td>
<td>NDC:51660-204-21</td>
<td>20 in 1 BLISTER PACK; Type 0: Not a Combination Product</td>
<td>04/28/2006</td>
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### Marketing Information
- **Marketing Category**: ANDA
- **Application Number or Monograph Citation**: ANDA077442
- **Marketing Start Date**: 04/28/2006
- **Marketing End Date**: |

**Labeler** - Ohm Laboratories Inc. (184769029)

**Registrant** - Ohm Laboratories Inc. (184769029)
<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>ID/FEI</th>
<th>Business Operations</th>
</tr>
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<tbody>
<tr>
<td>Ohm Laboratories Inc.</td>
<td></td>
<td>051565745</td>
<td>manufacture(51660-204)</td>
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Revised: 3/2019