PSEUDOEPHEDRINE HYDROCHLORIDE - pseudoephedrine hcl tablet, film coated, extended release
Perrigo New York Inc

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Perrigo Pseudoephedrine Hydrochloride 120 mg Drug Facts

Active ingredient (in each tablet)
Pseudoephedrine HCl 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

- **each tablet contains**: calcium 45 mg
- store at 20-25°C (68 - 77°F) in a dry place
- protect from light
- **do not use if blister unit is broken or torn**
- see carton end panel for lot number and expiration date
- this product meets the requirements of USP Drug Release Test 3

## Inactive ingredients

carnauba wax, colloidal silicon dioxide, dibasic calcium phosphate dihydrate, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, titanium dioxide

## Questions or comments?

1-800-719-9260

## Principal Display Panel

Compare to Sudafed® Sinus Congestion 12 Hour active ingredient

Pseudoephedrine Hydrochloride Extended Release Tablets 120 mg

Nasal Decongestant

Maximum Strength – Non-Drowsy

Sinus Pressure – Congestion

10 COATED CAPLETS*  
120 mg EACH

actual size

*(Capsule-shaped Tablets)

12 Hour Sinus
Pseudoephedrine Hydrochloride Extended Release Tablets
120 mg Nasal Decongestant

Maximum Strength • Non-Drowsy
Sinus Pressure • Congestion

10 COATED CAPLETS* 120 mg EACH
*(Capsule-shaped Tablets)

Compare to Sudafed®
Sinus Congestion 12 Hour
active ingredient

Perrigo®
NDC 45802-107-52

12 Hour Sinus
### Product Information

**Product Type**: HUMAN OTC DRUG  
**Route of Administration**: ORAL  
**Item Code (Source)**: NDC:45802-107

### Active Ingredient/Active Moiety

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

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
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<tbody>
<tr>
<td>CARNAUBA WAX (UNII: R12CBM0EIZ)</td>
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<tr>
<td>SILICON DIOXIDE (UNII: ETJ7Z6XBU4)</td>
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<tr>
<td>DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)</td>
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<td>HYPRO MELLOSES (UNII: 3NW29V3WO)</td>
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<tr>
<td>MAGNESIUM STEARATE (UNII: 70097M6B0)</td>
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<tr>
<td>CELLULOSE, MICROCRYSTALLINE (UNII: 0PIR32D61U)</td>
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<tr>
<td>POLYETHYLENE GLYCOL (UNII: 3WJQ05DW1A)</td>
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## POLYSORBATE 80 (UNII: 6OZP39ZG8H)

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

### Product Characteristics

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<th>Value</th>
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<tbody>
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### Packaging

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<th>Marketing End Date</th>
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<td>NDC:45802-107-52</td>
<td>10 in 1 CARTON</td>
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<tr>
<td>1</td>
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<td>1 in 1 BLISTER PACK; Type 0: Not a Combination Product</td>
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### Marketing Information

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<td>ANDA</td>
<td>ANDA075153</td>
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**Labeler** - Perrigo New York Inc (078846912)

Revised: 4/2019