

**PSEUDOEPHEDRINE HYDROCHLORIDE- pseudoephedrine hydrochloride tablet,  
film coated, extended release  
Amerisource Bergen**

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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	<ul style="list-style-type: none"><li>▪ take 1 tablet every 12 hours</li><li>▪ do not take more than 2 tablets in 24 hours</li></ul>
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:  
AmerisourceBergen  
1 West First Avenue  
Conshohocken, PA 19428

## PRINCIPAL DISPLAY PANEL - 120 mg Tablet Blister Pack Carton

GOOD  
NEIGHBOR  
PHARMACY®

Compare to active ingredient in  
Sudafed® 12 hour\*

NDC 46122-166-60

12 HOUR

Non-Drowsy  
Pseudoephedrine  
Hydrochloride 120 mg  
Extended-Release Tablets, USP  
Long-Acting Nasal Decongestant

- SINUS PRESSURE + CONGESTION
- MAXIMUM STRENGTH

20 Coated Capsule-Shaped Tablets 120 mg Each

**Drug Facts**

**Active ingredient**  
(in each tablet)  
Pseudoephedrine HCl, USP 120 mg.....Nasal decongestant

**Uses**  
temporarily relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies

**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

**dosage**  
When using this product do not exceed recommended dosage

**Questions?** call 1-800-406-7984

**Inactive ingredients**  
cellulose, colloidal silicon dioxide, hypromellose, croscarmellose, magnesium stearate, titanium dioxide

**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.

**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

**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)

**Stop use and ask a doctor if**  
■ symptoms do not improve within 7 days or occur with a fever  
■ nervousness, dizziness, or sleeplessness occur  
■ pregnant or breast-feeding, ask a health professional before use.

**Drug Facts (continued)**

**12 HOUR**

**Pseudoephedrine Hydrochloride 120 mg**

**Extended-Release Tablets, USP**

**12 HOUR**

**Pseudoephedrine Hydrochloride 120 mg**

**Extended-Release Tablets, USP**

**Long-Acting Nasal Decongestant**

- SINUS PRESSURE + CONGESTION
- MAXIMUM STRENGTH

**20 Coated Capsule-Shaped Tablets 120 mg Each**

**12 HOUR**

**Compare to active ingredient in Sudafed® 12 Hour\***

**NON VARNISH**

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# PSEUDOEPHEDRINE HYDROCHLORIDE

pseudoephedrine hydrochloride tablet, film coated, extended release

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:46122-166
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>PSEUDOEPHEDRINE HYDROCHLORIDE</b> (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII: 7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	120 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>CASTOR OIL</b> (UNII: D5340Y2I9G)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

## Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	18mm
<b>Flavor</b>		<b>Imprint Code</b>	204
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:46122-166-60	20 in 1 BLISTER PACK; Type 0: Not a Combination Product	04/28/2006	

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA	ANDA077442	04/28/2006	

**Labeler** - Amerisource Bergen (007914906)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Ohm Laboratories Inc.		051565745	manufacture(46122-166)

Revised: 6/2021

Amerisource Bergen