PSEUDOEPHEDRINE HYDROCHLORIDE- pseudoephedrine hydrochloride tablet, film coated, extended release

Amerisource Bergen

Drug Facts

ACTIVE INGREDIENT (IN EACH TABLET)

Pseudoephedrine HCl USP, 120 mg

PURPOSE

Nasal decongestant

USES

Temporarily relieves nasal congestion due to:

- common cold
- hay fever
- upper respiratory allergies
- temporarily restores freer breathing through the nose
- promotes nasal and/or sinus drainage
- 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
- diabetes
- thyroid disease
- trouble urinating due to an enlarged prostate gland

When using this product

do not use more than directed

Stop use and ask a doctor if

- symptoms do not get better within 7 days or occur with a fever
- you get nervous, dizzy, or sleepless

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.

DIRECTIONS

- adults and children 12 years and older: 1 tablet every 12 hours; not more than 2 tablets in 24 hours
- children under 12 years: ask a doctor

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

PRINCIPAL DISPLAY PANEL

GOOD NEIGHBOR PHARMACY®

Compare to active ingredient in Sudafed® 12 hour*

NDC 46122-0166-60

Non-Drowsy

12 HOUR

Pseudoephedrine Hydrochloride 120 mg

Extended-Release Tablets, USP

Long-Acting Nasal Decongestant

- Nas al and Sinus Congestion due to Colds & Allergies
- Sinus Pressure
- Maximum Strength

20 Coated Capsule-Shaped Tablets 120 mg Each

Distributed by: AmerisourceBergen

5098863/R1012



PSEUDOEPHEDRINE HYDROCHLORIDE

pseudoephedrine hydrochloride tablet, film coated, extended release

Product Information

Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:46122-166
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
PSEUDO EPHEDRINE HYDRO CHLO RIDE (PSEUDO EPHEDRINE)	PSEUDOEPHEDRINE HYDROCHLORIDE	120 mg	

Inactive Ingredients				
Ingredient Name	Strength			
CASTOR OIL				
COLLO IDAL SILICON DIO XIDE				
HYPROMELLOSES				
CELLULO SE, MICRO CRYSTALLINE				
MAGNESIUM STEARATE				
TITANIUM DIO XIDE				

Product Characteristics				
Color	white	Score	no score	
Shape	CAPSULE	Size	18 mm	
Flavor		Imprint Code	204	
Contains				

ı	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:46122-166-60	20 in 1 BLISTER PACK		

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

Labeler - Amerisource Bergen (007914906)

Registrant - Ranbaxy Pharmaceuticals Inc. (937890044)

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

Revised: 10/2012 Amerisource Bergen