

PSEUDOEPHEDRINE HYDROCHLORIDE- pseudoephedrine hydrochloride tablet, coated
AAA Pharmaceutical, Inc.

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.

Pseudoephedrine HCl Tablets

Drug Facts

Active ingredient (in each tablet)

Pseudoephedrine HCl 30 mg

Purpose

Nasal decongestant

Uses

- temporarily relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies, and nasal congestion associated with sinusitis
- 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 use more than directed**

Stop use and ask a doctor if

- you get nervous, dizzy, or sleepless
- symptoms do not improve within 7 days or are accompanied by 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.

Directions

adults and children 12 years of age and over	<ul style="list-style-type: none"> ▪ take 2 tablets every 4 to 6 hours ▪ do not take more than 8 tablets in 24 hours
children 6 to under 12 years of age	<ul style="list-style-type: none"> ▪ take 1 tablet every 4 to 6 hours ▪ do not take more than 4 tablets in 24 hours
children under 6 years of age	<ul style="list-style-type: none"> ▪ ask a doctor

Other information

- each tablet contains: **calcium 25 mg**
- store at 15°-25°C (59°-77°F) in a dry place
- retain carton for complete product information

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, D&C red #27, dibasic calcium phosphate, FD&C red #40, FD&C yellow #6, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, titanium dioxide

Distributed by:

AAA Pharmaceutical, Inc.
681 Main Street
Lumberton, NJ 08048

PRINCIPAL DISPLAY PANEL - 24 Tablet Blister Pack Carton

RESTORE u

NDC 57344-035-02

†COMPARE TO THE ACTIVE
INGREDIENT IN SUDAFED®
NASAL DECONGESTANT

***MAXIMUM
STRENGTH***

NON- DROWSY

Nasal Decongestant

Pseudoephedrine HCl

Relieves: • Nasal & Sinus Congestion • Sinus Pressure

24 TABLETS - 30 mg each

NC

NC

NC

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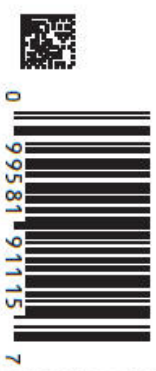
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Drug Facts (continued)

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RESTORE *u* **Nasal** MAXIMUM STRENGTH
Decongestant
Pseudoephedrine HCl
24 TABLETS - 30 mg each



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Decongestant
Pseudoephedrine HCl
Relieves: • Nasal & Sinus Congestion • Sinus Pressure
24 TABLETS - 30 mg each

†COMPARE TO THE ACTIVE INGREDIENT IN SLIDATED® NASAL DECONGESTANT

NON-DROWSY

Distributed by:
AAA Pharmaceutical, Inc.
681 Main Street
Lumberton, NJ 08048

†This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Sudafed® Congestion.

DO NOT USE IF BLISTER UNITS ARE TORN OR BROKEN

F103502RES_R0

RESTORE *u* **Nasal** MAXIMUM STRENGTH
Decongestant
Pseudoephedrine HCl
24 TABLETS - 30 mg each

PSEUDOEPHEDRINE HYDROCHLORIDE

pseudoephedrine hydrochloride tablet, coated

Product Information

Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:57344-035
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PSEUDOEPHEDRINE HYDROCHLORIDE (PSEUDOEPHEDRINE)	PSEUDOEPHEDRINE HYDROCHLORIDE	30 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE	
CROSCARMELLOSE SODIUM	
D&C RED NO. 27	
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS	
FD&C RED NO. 40	
FD&C YELLOW NO. 6	
HYPROMELLOSES	
MAGNESIUM STEARATE	
CELLULOSE, MICROCRYSTALLINE	
POLYETHYLENE GLYCOLS	
TITANIUM DIOXIDE	

Product Characteristics

Color	RED	Score	no score
Shape	ROUND	Size	7mm
Flavor		Imprint Code	A;035
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57344-035-02	1 in 1 CARTON		
1		24 in 1 BLISTER PACK		
2	NDC:57344-035-03	2 in 1 CARTON		
2		24 in 1 BLISTER PACK		
3	NDC:57344-035-04	4 in 1 CARTON		
3		24 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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OTC MONOGRAPH FINAL

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Labeler - AAA Pharmaceutical, Inc. (181192162)

Revised: 1/2013

AAA Pharmaceutical, Inc.