

PSEUDOEPHEDRINE HYDROCHLORIDE- pseudoephedrine hydrochloride tablet, extended release

HEB

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">▪ 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**

PRINCIPAL DISPLAY PANEL - 120 mg Tablet Blister Pack Carton

**Compare to Sudafed® 12 Hour active ingredient

NDC 37808-007-69

H-E-B®

MAXIMUM STRENGTH

12 Hour Decongestant

Pseudoephedrine Hydrochloride
Extended-Release Tablets USP, 120 mg

Long-Acting Nasal Decongestant

Non-Drowsy

Relief of:

- SINUS PRESSURE + CONGESTION

20 COATED CAPSULE-SHAPED TABLETS

120mg EACH

actual
size

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<p>Directions adults and children ■ take 1 tablet every 12 hours in 12 years and over ■ do not take more than 2 tablets in 24 hours</p>	<p>children under 12 years ■ do not use this product in children under 12 years of age</p>
<p>Drug Facts (continued) Stop use and ask a doctor if: ■ symptoms do not improve within 7 days or occur with a fever ■ nervousness, dizziness, or sleeplessness occur ■ nasal decongestant use 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)</p>	
<p>Drug Facts Active ingredient (in each tablet) Pseudoephedrine HCl, USP 120 mg.....Nasal decongestant</p>	
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<p>Warnings Do not use if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychotic 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 prostatic gland</p>	
<p>When using this product do not exceed recommended dosage</p>	

H-E-B
Maximum Strength
12 Hour Decongestant
 Pseudoephedrine Hydrochloride
 Extended-Release Tablets USP, 120 mg
Long-Acting Nasal Decongestant

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120mg EACH



actual size

Expiration Date
NON VARNISH
 Batch No.

** All trademarks are property of their respective owners. This product is not affiliated with the makers/owners of Sudafed® 12 Hour.

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Maximum Strength
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PSEUDOEPHEDRINE HYDROCHLORIDE
 pseudoephedrine hydrochloride tablet, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37808-007
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

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

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37808-007-69	1 in 1 CARTON	05/15/2019	
1		20 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077442	05/15/2019	

Labeler - HEB (007924756)**Registrant** - Ohm Laboratories Inc. (184769029)**Establishment**

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		184769029	manufacture(37808-007)

Revised: 5/2019

HEB