PSEUDOEPHEDRINE HCL - pseudoephedrine hcl tablet, extended release
Aurohealth LLC

Pseudoephedrine HCl Extended-Release Tablets USP 120 mg

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	• 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 36 mg
- store at 20° to 25°C (68° to 77°F). Protect from light.
- do not use if the individual blister unit is open or torn
- see side panel for lot number and expiration date
- Meets USP dissolution test 4

Inactive ingredients

colloidal silicon dioxide, dibasic calcium phosphate dihydrate, hydroxypropyl cellulose, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, talc, and titanium dioxide.

Questions or comments?

call **1-855-274-4122**

Distributed by:
AUROHEALTH LLC
2572 Brunswick Pike
Lawrenceville, NJ 08648

Made in India
Code: TS/DRUGS/22/2009

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 120 mg, Blister Carton 20 (2 X 10) Extended-Release Tablets

AUROHEALTH
Compare to the active ingredient in
Sudafed® 12 Hour**
NDC 58602-804-67
MAXIMUM STRENGTH
Long-Acting Nasal Decongestant
Pseudoephedrine HCl
Extended-Release Tablets USP 120 mg

- **SINUS PRESSURE**
- **CONGESTION**
- **NON-DROWSY**

12 HOUR
20 COATED CAPLETS*
120 mg EACH
***CAPSULE-SHAPED TABLETS**

PSEUDOEPHEDRINE HCL

pseudoephedrine hcl tablet, extended release

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58602-804
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
HYDROXYPROPYL CELLULOSE (90000 WAMW) (UNII: UKE75GEA7F)	
HYPROMELLOSE 2208 (15000 MPA.S) (UNII: Z78RG6M2N2)	
HYPROMELLOSE 2208 (4000 MPA.S) (UNII: 39J80LT57T)	
HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE (White to Off-white)	**Score**	no score
Shape	CAPSULE	**Size**	18mm
Flavor		**Imprint Code**	70;T
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-804-83	1 in 1 CARTON	06/09/2017	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:58602-804-67	2 in 1 CARTON	06/09/2017	
2		10 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	ANDA209008	06/09/2017	

Labeler - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(58602-804) , MANUFACTURE(58602-804)

Revised: 11/2022 Aurohealth LLC