

**PSEUDOEPHEDRINE HYDROCHLORIDE - pseudoephedrine
hydrochloride tablet, extended release
Aurohealth LLC**

Pseudoephedrine Hydrochloride Extended-Release Tablets, USP 240 mg

Drug Facts

Active ingredient (in each tablet)

Pseudoephedrine Hydrochloride USP 240 mg

Purpose

Nasal decongestant

Uses

- temporarily relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies
- reduces swelling of nasal passages
- relieves sinus 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
- had obstruction or narrowing of the bowel Rarely, tablets of this kind may cause bowel obstruction (blockage), usually in people with severe narrowing of the bowel (esophagus, stomach or intestine).

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

- you experience persistent abdominal pain or vomiting

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"> • swallow one whole tablet with water every 24 hours • do not exceed one tablet in 24 hours • do not divide, crush, chew or dissolve the tablet • the tablet does not completely dissolve and may be seen in the stool (this is normal)
children under 12 years	do not use this product in children under 12 years of age

Other information

- store at 20° to 25°C (68° to 77°F).
- **do not use if the individual blister unit is open or torn**
- see side panel for lot number and expiration date
- FDA approved dissolution test specifications differ from USP.

Inactive ingredients

black iron oxide, cellulose acetate, colloidal silicon dioxide, dibutyl sebacate, glyceryl mono and dicaprylocaprate, hypromellose, lactose monohydrate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol-part. hydrolyzed, propylene glycol, shellac, sodium lauryl sulfate, stearic acid, talc and titanium dioxide.

Questions or comments?

call **1-855-274-4122** (Monday - Friday 8:30 AM to 5:00 PM EST)

Distributed by:

AUROHEALTH LLC

279 Princeton-Hightstown Road
East Windsor, NJ 08520

Made in India

Code: TS/DRUGS/22/2009

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 2 x 5 Blister Carton Label
AUROHEALTH

NDC 58602-884-58

#Compare to the active
ingredient in Sudafed® Sinus Congestion 24 Hour.

Pseudoephedrine Hydrochloride
Extended-Release Tablets, USP 240 mg
Nasal Decongestant

MAXIMUM STRENGTH

24
HOUR

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

Actual Size

2 x 5 tablets per blister card

Route of Administration		ORAL		
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII: 7CUC9DDI9F)		PSEUDOEPHEDRINE HYDROCHLORIDE	240 mg	
Inactive Ingredients				
Ingredient Name			Strength	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)				
CELLULOSE ACETATE (UNII: 3J2P07GVB6)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
DIBUTYL SEBACATE (UNII: 4W5IH7FLNY)				
GLYCERYL MONO- AND DICAPRYLOCAPRATE (UNII: U72Q2I8C85)				
HYPROMELLOSE 2208 (100000 MPA.S) (UNII: VM7F0B23ZI)				
HYPROMELLOSE 2910 (3 MPA.S) (UNII: 0VUT3PMY82)				
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)				
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
SHELLAC (UNII: 46N107B71O)				
SODIUM LAURYL SULFATE (UNII: 368GB5141J)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
TALC (UNII: 7SEV7J4R1U)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
Product Characteristics				
Color	WHITE (white to off-white)	Score	no score	
Shape	ROUND (biconvex)	Size	11mm	
Flavor		Imprint Code	P240	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-884-58	2 in 1 CARTON	12/29/2025	
1		5 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:58602-884-27	1 in 1 CARTON	12/29/2025	
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	ANDA218854	12/29/2025	

Labeler - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(58602-884) , MANUFACTURE(58602-884)

Revised: 1/2026

Aurohealth LLC