

**PSEUDOEPHEDRINE HCL - pseudoephedrine hcl tablet, extended release  
Better Living Brands LLC**

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**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	<ul style="list-style-type: none"><li>• take 1 tablet every 12 hours</li><li>• do not take more than 2 tablets in 24 hours</li></ul>
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:**

BETTER LIVING BRANDS LLC  
P.O.BOX 99  
PLEASANTON, CA 94566-0009  
†1-888-723-3929

Made in India

Code: TS/DRUGS/22/2009

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

**Compare to the  
Sudafed® 12 Hour\*\***  
active ingredient

NDC 21130-158-67

12 HOUR  
MAXIMUM STRENGTH

Long-Acting  
Nasal Decongestant  
PSEUDOEPHEDRINE HCl  
Extended-Release Tablets USP  
120 mg

- SINUS PRESSURE
- CONGESTION
- NON-DROWSY

20 COATED CAPLETS\*

120 mg EACH

\*CAPSULE-SHAPED TABLETS

GLUE - NO COATING

**Drug Facts** (continued)

**Drug Facts (continued)**

**Warnings**

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- 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

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Scan here for more information



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**Long-Acting  
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NDC 21130-158-67

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- CONGESTION
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52407



P1052407 LM-5297 NWZ

Lot: Exp.:



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†1-888-23-3929  
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\*\*This product is not manufactured or distributed by McNeil Consumer Healthcare Division of McNeil-PPC, Inc. distributor of Sudafed® 12 Hour.

# PSEUDOEPHEDRINE HCL

pseudoephedrine hcl tablet, extended release

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:21130-158
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

Ingredient Name	Strength
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>DIBASIC CALCIUM PHOSPHATE DIHYDRATE</b> (UNII: O7TSZ97GEP)	
<b>HYDROXYPROPYL CELLULOSE (90000 WAMW)</b> (UNII: UKE75GEA7F)	
<b>HYPROMELLOSE 2208 (15000 MPA.S)</b> (UNII: Z78RG6M2N2)	
<b>HYPROMELLOSE 2208 (4000 MPA.S)</b> (UNII: 39J80LT57T)	
<b>HYPROMELLOSE 2910 (5 MPA.S)</b> (UNII: R75537T0T4)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

## Product Characteristics

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

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21130-158-67	2 in 1 CARTON	09/01/2023	
1		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
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ANDA	ANDA209008	09/01/2023	
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**Labeler** - Better Living Brands LLC (009137209)

**Registrant** - Aurohealth LLC (078728447)

**Establishment**

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(21130-158) , MANUFACTURE(21130-158)

Revised: 7/2024

Better Living Brands LLC