

PSEUDOEPHEDRINE HYDROCHLORIDE- pseudoephedrine hydrochloride tablet, film coated, extended release

Safeway Inc.

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

- 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 **1-888-723-3929**

DISTRIBUTED BY
BETTER LIVING BRANDS LLC
P.O. BOX 99, PLEASANTON, CA
94566-0009

PRINCIPAL DISPLAY PANEL - 120 mg Tablet Blister Pack Carton

NDC 21130-204-21

Signature™

care

Quality Guaranteed

12 HOUR | MAXIMUM STRENGTH

Pseudoephedrine

Hydrochloride 120 mg

Extended-Release Tablets, USP

Long-Acting Nasal Decongestant

Actual Size

Compare to

Sudafed®

12 Hour

active ingredient†

- Sinus pressure + Congestion
- Non-drowsy

20 COATED CAPSULE-SHAPED TABLETS 120 mg EACH

Drug Facts

Active ingredient
(in each tablet)
Pseudoephedrine HCl, USP 120 mg.....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

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 sleepiness occur
 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
 ■ 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 1-888-723-3929)

12 HOUR | MAXIMUM STRENGTH

Signature care
Quality Guaranteed


Pseudoephedrine Hydrochloride 120 mg
Extended-Release Tablets, USP
Long-Acting Nasal Decongestant

NDC 21130-204-21

Signature care
Quality Guaranteed

12 HOUR | MAXIMUM STRENGTH

Pseudoephedrine Hydrochloride 120 mg
Extended-Release Tablets, USP
Long-Acting Nasal Decongestant



Actual Size

Compare to Sudafed® 12 Hour active ingredient*

- Sinus pressure + Congestion
- Non-drowsy

20 COATED CAPSULE-SHAPED TABLETS 120 mg EACH

Expiration Date: _____
Batch No. _____

Keep the carton. It contains important information. See end panel for expiration date.

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

DISTRIBUTED BY
 BETTERLIVING BRANDS LLC
 P.O. BOX 99, PLEASANTON, CA
 94566-0099
 1-888-723-3929
 www.betterlivingbrandllc.com
 RD 19064 S 3289

OUR PROMISE
 QUALITY & SATISFACTION
 100% GUARANTEED
 OR YOUR MONEY BACK!

PSEUDOEPHEDRINE HYDROCHLORIDE
 pseudoephedrine hydrochloride tablet, film coated, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21130-204
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DD19F)	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:21130-204-21	20 in 1 BLISTER PACK; Type 0: Not a Combination Product	04/28/2006	
2	NDC:21130-204-69	10 in 1 BLISTER PACK; Type 0: Not a Combination Product	04/28/2006	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077442	04/28/2006	

Labeler - Safeway Inc. (009137209)**Registrant** - Ohm Laboratories Inc. (184769029)**Establishment**

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		051565745	MANUFACTURE(21130-204)

