

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

Safeway Inc.

Drug Facts

ACTIVE INGREDIENT (IN EACH TABLET)

Pseudoephedrine HCL, USP 120 mg

PURPOSE

Nasal decongestant

USES

Temporarily relieves nasal congestion due to:

- common cold
- hay fever
- upper respiratory allergies
- temporarily restores freer breathing through the nose
- promotes nasal and/or sinus drainage
- 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
- diabetes
- thyroid disease
- trouble urinating due to an enlarged prostate gland

When using this product

- **do not use more than directed**

Stop use and ask a doctor if

- symptoms do not get better within 7 days or occur with a fever
- you get nervous, dizzy, or sleepless

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 older: 1 tablet every 12 hours; not more than 2 tablets in 24 hours
- children under 12 years: ask a doctor

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

PRINCIPAL DISPLAY PANEL

NDC 21130-204-69

12 HOUR MAXIMUM STRENGTH

Pseudoephedrine Hydrochloride 120 mg

Extended-Release Tablets, USP

Long-Acting Nasal Decongestant

Compare to SUDAFED® 12 Hour active ingredient†

- **Nasal & Sinus Congestion Due to Colds or Allergies**
- **Sinus Pressure**
- **Non-Drowsy**

10 COATED CAPSULE SHAPED TABLETS 120 mg EACH

SAFEWAY® care

DISTRIBUTED BY SAFEWAY INC.

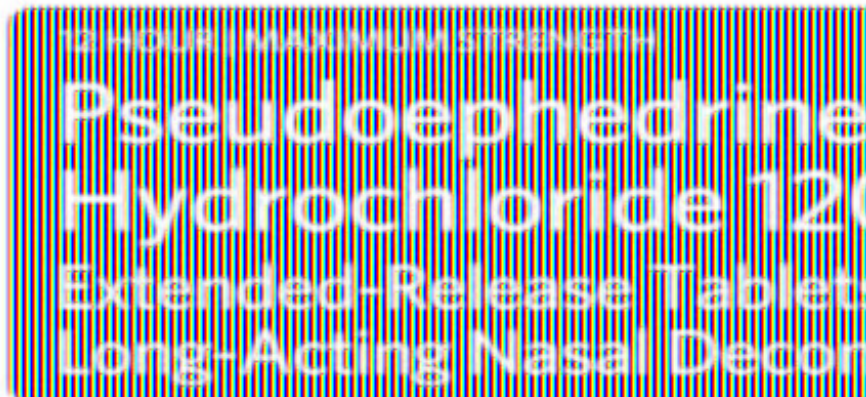
5115098/0115



Quality Guaranteed



Actual Size



Compare to
Sudafed[®]
12 Hour
active ingredient[†]

- Nasal & sinus congestion relief
- Sinus pressure
- Non-drowsy

10 COATED CAPSULE-SHAPED TABLETS 120 mg

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:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	120 mg

Inactive Ingredients

Ingredient Name	Strength
CASTOR OIL (UNII: D5340Y2I9G)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
CELLULOSE, MICROCRYSTALLINE (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		
2	NDC:21130-204-69	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	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)

Revised: 2/2015

Safeway Inc.