

PSEUDOEPHEDRINE HYDROCHLORIDE- pseudoephedrine hydrochloride tablet, film coated, extended release
Meijer Distribution, 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.

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 **1-800-406-7984**

PRINCIPAL DISPLAY PANEL

NDC 41250-204-69

Compare to Sudafed® 12 Hour active ingredient*

meijer™

Non-Drowsy

Maximum Strength

12 Hour Decongestant

Pseudoephedrine Hydrochloride 120 mg Extended-Release Tablets, USP

Long-Acting

Nasal Decongestant

Nasal & Sinus Congestion

Due to Colds & Allergies

Sinus Pressure

10 Coated Capsule-Shaped Tablets

120 mg Each

DIST. BY MEIJER

5102550/R0413

Questions? call 1-800-406-7984

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 ■ adults and children 12 years and older: 1 tablet every 12 hours; not more than 2 tablets in 24 hours
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Drug Facts (continued)
 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).

Drug Facts
Active ingredient
 Pseudoephedrine HCl, USP 120 mg.....Nasal decongestant
(in each tablet)

Purpose

Uses temporarily relieves nasal congestion due to:
 ■ common cold
 ■ hay fever
 ■ upper respiratory allergies
 ■ temporarily restores free breathing through the nose
 ■ promotes nasal and/or sinus drainage
 ■ temporarily relieves sinus congestion and pressure

Warnings
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 Ask a doctor before use if you have
 ■ heart disease
 ■ high blood pressure
 ■ diabetes
 ■ thyroid disease
 ■ trouble urinating due to an enlarged prostate gland

meijer **12Hour Decongestant**
 Pseudoephedrine Hydrochloride 120 mg Extended-Release Tablets, USP

NDC 41250-204-69

meijer

DIST. BY MEIJER
 DISTRIBUTION, INC.,
 2929 WALKER AVE NW
 GRAND RAPIDS, MI 49544
 www.meijer.com

10 Coated Capsule-Shaped Tablets
 120 mg Each

Compare to Sudafed® 12 Hour
 active ingredient*

**Non-Drowsy
 Maximum Strength**

12Hour Decongestant
 Pseudoephedrine Hydrochloride 120 mg Extended-Release Tablets, USP

**Long-Acting
 Nasal Decongestant**
 Nasal & Sinus Congestion
 Due to Colds & Allergies
 Sinus Pressure

Expiration Date:

Batch No.

NON VARNISH

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

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



pseudoephedrine hydrochloride tablet, film coated, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41250-204
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)	
COLLOIDAL 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:41250-204-69	1 in 1 CARTON		
1		10 in 1 BLISTER PACK		
2	NDC:41250-204-20	1 in 1 CARTON		
2		20 in 1 BLISTER PACK		

Marketing Information

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

Labeler - Meijer Distribution, Inc. (006959555)

Registrant - Ranbaxy Pharmaceuticals Inc. (937890044)

Establishment

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		051565745	manufacture(41250-204)

Revised: 5/2013

Meijer Distribution, Inc.