

PSEUDOEPHEDRINE HYDROCHLORIDE - pseudoephedrine hydrochloride tablet, film coated

Physicians Total Care, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

**SudoGest
Nasal Decongestant**

Active ingredient

Pseudoephedrine HCl 60 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

- diabetes
- thyroid disease
- heart disease
- high blood pressure
- trouble urinating due to enlargement of the prostate gland

When using this product

- **do not exceed recommended dose**

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- symptoms do not improve within 7 days or occur with 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.

Directions

- adults and children 12 years and older: take 1 tablet every 4 to 6 hours. Do not take more than 4 tablets in 24 hours.
- children under 12 years of age: do not use

Other information

- store at controlled room temperature 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

Inactive ingredients

corn starch, hypromellose, lactose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, silicon dioxide, stearic acid

Principal display panel

The product packaging shown below represents a sample of that currently in use. Additional packaging may also be available

FOR PHARMACY USE ONLY.

NOT FOR RETAIL SALE.

NDC 54868-1973-1



Pseudoephedrine Hydrochloride 60 mg

NASAL DECONGESTANT 60 mg

Relieves Nasal and Sinus Congestion due to Colds or Hay Fever

Without Drowsiness

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

50844 Rev. 0807L11302

Distributed by **Major Pharmaceuticals**

31778 Enterprise Drive

Livonia, MI 48150 USA M-17

Rev. 10/10 Re-order No. 700324

Relabeling and Repackaging by:
Physicians Total Care, Inc.
Tulsa, Oklahoma 74146

PSEUDOEPHEDRINE HYDROCHLORIDE

pseudoephedrine hydrochloride tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54868-1973(NDC:0904-5125)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	60 mg

Inactive Ingredients

Ingredient Name	Strength
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE (UNII: J2B2A4N98G)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	

Product Characteristics

Color	WHITE	Score	2 pieces
Shape	ROUND	Size	8mm
Flavor		Imprint Code	44;113
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54868-1973-1	20 in 1 BOTTLE		
2	NDC:54868-1973-3	100 in 1 BOTTLE		
3	NDC:54868-1973-4	30 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	11/25/2002	

Labeler - Physicians Total Care, Inc. (194123980)

Establishment

Name	Address	ID/FEI	Business Operations
Physicians Total Care, Inc.		194123980	relabel, repack

Revised: 1/2012

Physicians Total Care, Inc.