# 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.

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#### 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 pregrant 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

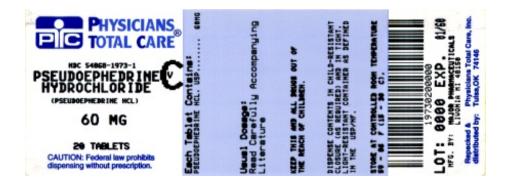
#### Principal display panel

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

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

<b>PSEUDOEPHEDR</b> pseudoephedrine hydrocl			RID	E					
<b>Product Information</b>									
Product Type		HUMAN OTC DRUG	G I	tem Code (Source)	NDC:54868	3-1973(1	73(NDC:0904-5125)		
Route of Administration		ORAL		. ,					
Active Ingredient/Act	tive Moie	ety							
	Ingre	dient Name			Basis of	of Strength		Strength	
<b>PSEUDO EPHEDRINE HYDF</b> - UNII:7CUC9DDI9F)	ROCHLORI	<b>DE</b> (UNII: 6 V9 V2RYJ	J8N) (H	PSEUDOEPHEDRINE	PSEUDOEPHED HYDROCHLOR			60 mg	
Inactive Ingredients									
		Ingredient N	Name				Strength		
HYPROMELLOSES (UNII: 3NXW29V3WO)									
LACTOSE (UNII: J2B2A4N9	8G)								
MAGNESIUM STEARATE (UNII: 70097M6I30)									
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)									
SILICON DIOXIDE (UNII: E	TJ7Z6XBU4	4)							
STEARIC ACID (UNII: 4ELV									
CELLULOSE, MICROCRY	STALLINE	(UNII: OP1R32D61U)	)						
Product Characterist	•								
			6			- ·			
Color	WHITE					2 pieces			
Shape	ROUN					8mm			
Flavor		Imprint Code			44;1	44;113			
Contains									
Packaging									
# Item Code	Package Description			Marketing Start Date		Marketing End Date		d Date	
1 NDC:54868-1973-1	20 in 1 BC	•		0			0		
2 NDC:54868-1973-3	100 in 1 B								
<b>3</b> NDC:54868-1973-4	30 in 1 BC	DTTLE							

Marketing Information								
Marketing Category Application Number or Monograph Citation		Marketing End Date						
part341	11/25/2002							
	Application Number or Monograph Citation	Application Number or Monograph Citation Marketing Start Date						

### Labeler - Physicians Total Care, Inc. (194123980)

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

Revised: 1/2012

Physicians Total Care, Inc.