# SUDOGEST - pseudoephedrine hydrochloride tablet Dispensing Solutions, 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

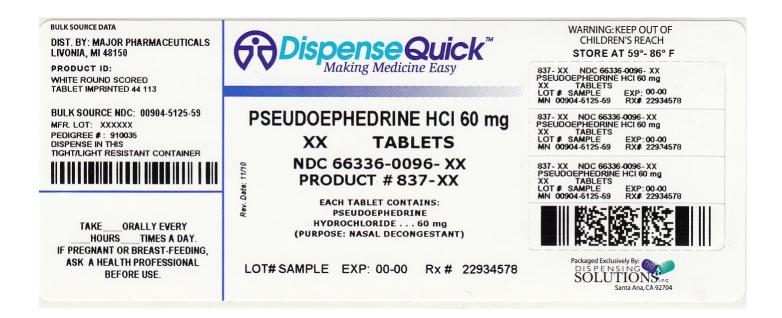
#### Other information

- 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



NDC 66336-0096-XX

NDC 66336-0096-20

NDC 66336-0096-30

#### Sudo Ges t<sup>TM</sup>

NASAL DECONGESTANT 60 mg

Pseudoephedrine Hydrochloride 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** 

Rev. 10/10 Re-order No. 700324

### **SUDOGEST**

pseudoephedrine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66336-096(NDC:0904-5125)
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
<b>PSEUDO EPHEDRINE HYDRO CHLO RIDE</b> (UNII: 6 V9 V2RYJ8 N) (PSEUDO EPHEDRINE - UNII:7CUC9 DDI9 F)	PSEUDOEPHEDRINE HYDROCHLORIDE	60 mg	

Inactive Ingredients			
Ingredient Name	Strength		
HYPROMELLOSES (UNII: 3NXW29 V3WO)			
LACTOSE (UNII: J2B2A4N98G)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)			
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)			
STEARIC ACID (UNII: 4ELV7Z65AP)			
CELLULO SE, MICRO CRYSTALLINE (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:66336-096-20	20 in 1 BOTTLE, PLASTIC		
2	NDC:66336-096-30	30 in 1 BOTTLE, PLASTIC		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part341	10/01/1994		
	- 11	0	Marketing End Da	

## **Labeler -** Dispensing Solutions, Inc. (066070785)

Establishment				
Name	Address	ID/FEI	Business Operations	
Dispensing Solutions, Inc.		066070785	relabel, repack	

Revised: 9/2011 Dispensing Solutions, Inc.