

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.

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

<p>BULK SOURCE DATA</p> <p>DIST. BY: MAJOR PHARMACEUTICALS LIVONIA, MI 48150</p> <p>PRODUCT ID: WHITE ROUND SCORED TABLET IMPRINTED 44 113</p> <p>BULK SOURCE NDC: 00904-5125-59 MFR. LOT: XXXXXX PEDIGREE #: 910035 DISPENSE IN THIS TIGHT/LIGHT RESISTANT CONTAINER</p>  <p>Rev. Date: 11/10</p>	 <p>PSEUDOEPHEDRINE HCl 60 mg XX TABLETS NDC 66336-0096-XX PRODUCT # 837-XX</p> <p>EACH TABLET CONTAINS: PSEUDOEPHEDRINE HYDROCHLORIDE . . . 60 mg (PURPOSE: NASAL DECONGESTANT)</p> <p>LOT# SAMPLE EXP: 00-00 Rx # 22934578</p>	<p>WARNING: KEEP OUT OF CHILDREN'S REACH STORE AT 59°- 86° F</p> <p>837- XX NDC 66336-0096- XX PSEUDOEPHEDRINE HCl 60 mg XX TABLETS LOT # SAMPLE EXP: 00-00 MN 00904-5125-59 RX# 22934578</p> <p>837- XX NDC 66336-0096- XX PSEUDOEPHEDRINE HCl 60 mg XX TABLETS LOT # SAMPLE EXP: 00-00 MN 00904-5125-59 RX# 22934578</p> <p>837- XX NDC 66336-0096- XX PSEUDOEPHEDRINE HCl 60 mg XX TABLETS LOT # SAMPLE EXP: 00-00 MN 00904-5125-59 RX# 22934578</p>  <p>Packaged Exclusively By: DISPENSING SOLUTIONS Santa Ana, CA 92704</p>
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NDC 66336-0096-XX
NDC 66336-0096-20
NDC 66336-0096-30

SudoGest™

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**

31778 Enterprise Drive

Livonia, MI 48150 USA M-17

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
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: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	

Labeler - Dispensing Solutions, Inc. (066070785)

Establishment

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

Revised: 9/2011

Dispensing Solutions, Inc.