SUDOGEST - pseudoephedrine hydrochloride tablet, film coated
H.J. Harkins Company, 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 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

MAJOR®

FOR PHARMACY USE ONLY.

NOT FOR RETAIL SALE.

NDC 0904-5125-59

SudoGest™

NASAL DECONGESTANT 60 mg

Pseudoephedrine Hydrochloride 60 mg

Relieves Nasal and Sinus Congestion due to Colds or Hay Fever

Without Drowsiness

100 TABLETS

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

50844 Rev. 0807L11302

Distributed by **Major Pharmaceuticals**

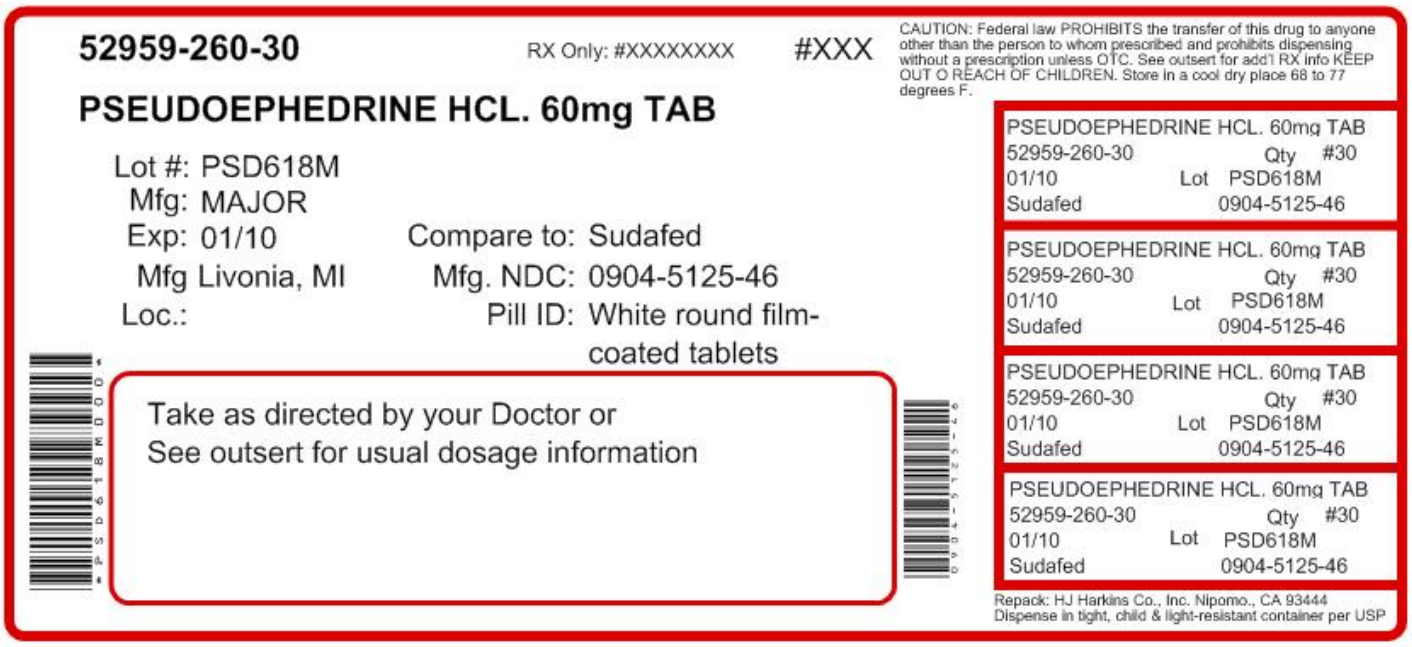
31778 Enterprise Drive

Livonia, MI 48150 USA M-17

Repacked by H.J. Harkins Company, Inc.

Nipomo, CA 93444

Rev. 10/11 Re-order No. 700324



Product Packaging

SUDOGEST

pseudoephedrine hydrochloride tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:52959-260(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:52959-260-00	100 in 1 BOTTLE, PLASTIC		
2	NDC:52959-260-20	20 in 1 BOTTLE, PLASTIC		
3	NDC:52959-260-24	24 in 1 BOTTLE, PLASTIC		
4	NDC:52959-260-25	25 in 1 BOTTLE, PLASTIC		
5	NDC:52959-260-30	30 in 1 BOTTLE, PLASTIC		
6	NDC:52959-260-40	40 in 1 BOTTLE, PLASTIC		
7	NDC:52959-260-60	60 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 - H.J. Harkins Company, Inc. (147681894)

Registrant - H.J. Harkins Company, Inc. (147681894)

Establishment

Name	Address	ID/FEI	Business Operations
H.J. Harkins Company, Inc.		147681894	repack, relabel

Revised: 1/2012 H.J. Harkins Company, Inc.