SUDOGEST- pseudoephedrine hydrochloride tablet, film coated A-S Medication Solutions

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 (in each tablet)

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
- heart disease
- high blood pressure
- thyroid disease
- trouble urinating due to an enlarged 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 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- use by expiration date on package

Inactive ingredients

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

Questions or comments?

(800) 616-2471

HOW SUPPLIED

Product: 50090-0155 NDC: 50090-0155-1 30 TABLET, FILM COATED in a BOTTLE NDC: 50090-0155-3 12 TABLET, FILM COATED in a BOTTLE NDC: 50090-0155-4 20 TABLET, FILM COATED in a BOTTLE NDC: 50090-0155-5 15 TABLET, FILM COATED in a BOTTLE

Pseudoephedrine Hydrochloride

line E	
HCL 60 MG	
GREES F	
SEE PACKAGE INSE 0035009001551	AT 5 X
	GREES F

Product Information	า						
Product Type	HUMAN O	TC DRUG	UG Item Code (Source) NDC:50090-015			5(NDC:0904-5125)	
Route of Administratio	n ORAL						
Active Ingredient/Ac	tive Moiety						
li li	ngredient Na	me		Basi	s of Strengt	h	Strengt
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N)PSEUDOEPHEDRINE(PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)HYDROCHLORIDE					60 mg		
Inactive Ingredients		dient Na	ame			St	rength
Ingredient Name HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)						5	rengti
MAGNESIUM STEARATE (U							
POLYETHYLENE GLYCOL,		NII: 3MQ0	SDW1A)				
SILICON DIOXIDE (UNII: ETJ	7Z6XBU4)						
STEARIC ACID (UNII: 4ELV72	Z65AP)						
MICROCRYSTALLINE CELL	ULOSE (UNII: OP:	LR32D61U)				
STARCH, CORN (UNII: 0823							
LACTOSE, UNSPECIFIED F	ORM (UNII: J2B2A	4N98G)					
Product Characteris	tics						
Color	WHITE	Sci	Nro.		2 piece	25	
Shape	ROUND				2 piece 8mm	•	
Flavor			orint Code		44;113	}	
					,=10		

Ρ	Packaging						
#	ltem Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:50090- 0155-1	30 in 1 BOTTLE; Type 0: Not a Combination Product	11/28/2014				
2	NDC:50090- 0155-3	12 in 1 BOTTLE; Type 0: Not a Combination Product	11/28/2014				
3	NDC:50090- 0155-4	20 in 1 BOTTLE; Type 0: Not a Combination 11/28/2014 Product					
4	NDC:50090- 0155-5	15 in 1 BOTTLE; Type 0: Not a Combination Product	11/28/2014				
5	NDC:50090- 0155-0	24 in 1 BOTTLE; Type 0: Not a Combination 10/01/2018 Product		10/31/2018			
Marketing Information							
	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
-	TC MONOGRAPH NAL	part341	12/07/1984				

Labeler - A-S Medication Solutions (830016429)

Establishment						
Name	Address	ID/FEI	Business Operations			
A-S Medication Solutions		830016429	RELABEL(50090-0155), REPACK(50090-0155)			

Revised: 4/2021

A-S Medication Solutions