SUDOGEST NASAL DECONGESTANT- pseudoephedrine hcl 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.

Major Pharmaceuticals SudoGest Nasal Decongestant Drug Facts

Active ingredient (in each tablet)

Pseudoephedrine HCl 30 mg

Purpose

Nasal decongestant

Uses

- temporarily relieves sinus congestion and pressure
- temporarily relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies

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

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland

When using this product

do not exceed recommended dosage

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- symptoms do not improve within 7 days or occur with a 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 (1-800-222-1222).

Directions

adults and children 12 years and over	• take 2 tablets every 4 to 6 hours • do not take more than 8 tablets in 24 hours
children ages 6 to 11 years	• take 1 tablet every 4 to 6 hours • do not take more than 4 tablets in 24 hours
children under 6 years	do not use this product in children under 6 years of age

Other information

- **each tablet contains:** calcium 20 mg
- store at 20˚-25˚C (68˚-77˚F)
- **do not use if blister unit is broken or torn**

Inactive ingredients

carnauba wax, dibasic calcium phosphate dihydrate, FD&C red no. 40 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, silicon dioxide, titanium dioxide

Questions or comments?

1-800-616-2471

HOW SUPPLIED

Product: 50090-4345

NDC: 50090-4345-1 1 TABLET, FILM COATED in a BLISTER PACK / 24 in a CARTON

NDC: 50090-4345-0 48 TABLET, FILM COATED in a BOTTLE

NDC: 50090-4345-2 12 TABLET, FILM COATED in a BOTTLE

NDC: 50090-4345-3 30 TABLET, FILM COATED in a BOTTLE

NDC: 50090-4345-4 4 TABLET, FILM COATED in a BOTTLE

NDC: 50090-4345-5 15 TABLET, FILM COATED in a BOTTLE

Pseudoephedrine HCl

SUDOGEST NASAL DECONGESTANT

pseudoephedrine hcl tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50090-4345(NDC:0904-6337)
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	30 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CARNAUBA WAX (UNII: R12CBM0EIZ)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

Product Characteristics

Color	RED	**Score**	no score
Shape	ROUND (convex)	**Size**	7mm
Flavor		**Imprint Code**	L432
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50090-4345-1	24 in 1 CARTON	06/10/2019	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:50090-4345-2	12 in 1 BOTTLE; Type 0: Not a Combination Product	10/09/2019	
3	NDC:50090-4345-5	15 in 1 BOTTLE; Type 0: Not a Combination Product	10/09/2019	
4	NDC:50090-4345-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	10/09/2019	
5	NDC:50090-4345-4	4 in 1 BOTTLE; Type 0: Not a Combination Product	10/09/2019	
6	NDC:50090-4345-0	48 in 1 BOTTLE; Type 0: Not a Combination Product	10/09/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	09/10/1991	

Labeler - A-S Medication Solutions (830016429)

Establishment

Name	Address	ID/FEI	Business Operations
A-S Medication Solutions		830016429	RELABEL(50090-4345)

Revised: 2/2023 A-S Medication Solutions