

SUDOGEST- pseudoephedrine hcl tablet, 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 30 mg Tablets

Active Ingredient

In each tablet Pseudoephedrine HCl 30 mg

Purpose

Nasal Decongestant

Keep out of reach of children

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away

Indications and Usage

INDICATIONS AND USAGE:

Temporarily relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies, and nasal congestion associated with sinusitis

Temporarily relieves sinus congestion and pressure

Warnings

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.

Dosage and Administration

DOSAGE AND ADMINISTRATION:

Directions – take every 4-6 hours -Do not take more than 4 does in 24 hours

Adults and children 12 years and over – 2 tablets

Children 6 to under 12 years – 1 tablet

Children under 6 years – do not use

Inactive Ingredients

INACTIVE INGREDIENTS: acacia, calcium sulfate, carnauba Wax. colloidal silicon dioxide, corn starch, D-C red no. 27, D-C yellow no.10, FD-C red no.40, FD-C yellow no 6, iron oxide black, iron oxide red, iron oxide yellow (iron oxide ochre) Kaolin, microcrystalline cellulose, polyethylene glycol (PEG) 400, , pregelatinized starch, sodium starch glycolate, stearic acid, sugar, talc, titanium

dioxide

Questions or Comments?

1-800-616-2471

Storage

Store at 25°C (77°F). Excursions permitted between 15°-30°C (59°-86°F).

Protect from light.

HOW SUPPLIED

Product: 50090-1955

NDC: 50090-1955-0 28 TABLET, COATED in a BOTTLE

PSEUDOEPHEDRINE HCL



SUDOGEST

pseudoephedrine hcl tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50090-1955(NDC:0904-6338)
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
ACACIA (UNII: 5C5403N26O)	
CALCIUM SULFATE ANHYDROUS (UNII: E934B3V59H)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
KAOLIN (UNII: 24H4NWX5CO)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	RED	Score	no score
Shape	ROUND	Size	6mm
Flavor		Imprint Code	TCL016
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50090-1955-0	28 in 1 BOTTLE; Type 0: Not a Combination Product	08/17/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	02/17/2014	

Labeler - A-S Medication Solutions (830016429)

Establishment

Name	Address	ID/FEI	Business Operations
A-S Medication Solutions		830016429	RELABEL(50090-1955) , REPACK(50090-1955)

