

SUDOGEST- pseudoephedrine hydrochloride tablet, film coated

Unit Dose Services

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 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 25°C (77°F); excursions permitted between 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

Questions or comments?

(800)-616-2471

HOW SUPPLIED

Product: 50436-0333

NDC: 50436-0333-2 24 TABLET, FILM COATED in a BOTTLE

SUDOGEST (PSEUDOEPHEDRINE HYDROCHLORIDE) TABLET, FILM COATED

NDC: 50436-0333-2

PSEUDOEPHEDRINE
HCL

60 MG

24 TAB



MFG BY: MAJOR

XXXX

MFG NDC: 00904-5125-59

MFG LOT: XXXX

LOT: XXXXX

EXP: XXXXX

WARNING: KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25°C (68-77°F) CONTROLLED ROOM TEMPERATURE. SEE PACKAGE INSERT FOR DOSAGE INFORMATION.

Pkg by: Unit Dose Services, LLC
Dania, FL 33004



NDC: 50436-0333-2 24 TAB
DRUG: PSEUDOEPHEDRINE
HCL

LOT: XXXXX EXP: XXXXX

NDC: 50436-0333-2 24 TAB
DRUG: PSEUDOEPHEDRINE
HCL 60 MG

LOT: XXXXX EXP: XXXXX

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SUDOGEST

pseudoephedrine hydrochloride tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50436-0333(NDC:0904-5125)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	60 mg
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Inactive Ingredients

Ingredient Name	Strength
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
MICROCRYSTALLINE CELLULOSE (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:50436-0333-2	24 in 1 BOTTLE; Type 0: Not a Combination Product	12/07/1984	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	12/07/1984	

Labeler - Unit Dose Services (831995316)

Establishment

Name	Address	ID/FEI	Business Operations
Unit Dose Services		831995316	REPACK(50436-0333) , RELABEL(50436-0333)

Revised: 2/2017

Unit Dose Services