SUDOGEST NASAL DECONGESTANT- pseudoephedrine hcl tablet, film coated Major Pharmaceuticals

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

Principal Display Panel

COMPARE TO the active ingredient of SUDAFED® CONGESTION

SudoGest TM

NASAL DECONGESTANT

Pseudoephedrine Hydrochloride

Nasal & Sinus Congestion

Sinus Pressure

Actual Size

MAXIMUM STRENGTH

NON-DROWSY

24 TABLETS 30 mg EACH

MAJOR° SudoGest

NASAL DECONGESTANT

Pseudoephedrine Hydrochloride

NDC 0904-6337-24

COMPARE TO the active ingredient of SUDAFED® CONGESTION*

MAJOR°

SAL DECONGESTAN

Pseudoephedrine Hydrochloride

- Nasal & Sinus Congestion
- Sinus Pressure



Actual Size

24 TABLETS 30 mg EACH

MAXIMUM STRENGTH

NON-DROWSY

Important: Re ad all product information before using. Keep this box for important information.

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Drug Facts (continued)

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Questions or comments? 1-800-616-2471

*Major® SudoGest™ is not nn anufactured or distributed by McN eil Con su mer Health ca re, d istributor o fSu dafed® Congestion.

Distributed by: MAJOR® PHARMACEUTICALS 17177 N Laurel Park Drive, Suite 2:33 Livon ia, MI48152

REV. 09/18 Re-Order No. 700951







SUDOGEST NASAL DECONGESTANT

pseudoephedrine hcl tablet, film coated

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:0904-6337

Route of Administration ORAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength PSEUDO EPHEDRINE HYDRO CHLO RIDE (UNII: 6 V9 V2RYJ8 N) (PSEUDO EPHEDRINE HYDRO CHLO RIDE HYDRO CHLO RIDE HYDRO CHLO RIDE 30 mg

Inactive Ingredients		
Ingredient Name	Strength	
CARNAUBA WAX (UNII: R12CBM0 EIZ)		
DIBASIC CALCIUM PHO SPHATE DIHYDRATE (UNII: O7TSZ97GEP)		
HYPROMELLOSES (UNII: 3NXW29V3WO)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)		
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)		
POLYSORBATE 80 (UNII: 6 OZP39 ZG8 H)		
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		

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

l	Packaging			
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1 NDC:0904-6337-24	24 in 1 CARTON	09/10/1991	
ı	1	1 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

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

Labeler - Major Pharmaceuticals (191427277)

Revised: 10/2018 Major Pharmaceuticals