

SUDOGEST 12 HOUR- pseudoephedrine hcl tablet, film coated, extended release

Major Pharmaceuticals

Major Pharmaceuticals SudoGest 12 HOUR Drug Facts

Active ingredient (in each tablet)

Pseudoephedrine HCl 120 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

- 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	<ul style="list-style-type: none">• take 1 tablet every 12 hours• do not take more than 2 tablets in 24 hours
children under 12 years	do not use this product in children under 12 years of age

Other information

- **each tablet contains:** calcium 45 mg
- store at 20-25°C (68-77°F) in a dry place
- protect from light
- **do not use if blister unit is broken or torn**
- see carton end panel for lot number and expiration date
- this product meets the requirements of USP Drug Release Test 3

Inactive ingredients

carnauba wax, colloidal silicon dioxide, dibasic calcium phosphate dihydrate, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, titanium dioxide

Questions or comments?

1-800-719-9260

Principal Display Panel

COMPARE TO the active ingredient of SUDAFED® SINUS CONGESTION 12 HOUR CAPLETS

Sinus

SudoGest 12 HOUR

Pseudoephedrine Hydrochloride Extended-Release Tablets, USP 120 mg

Nasal Decongestant

Sinus Pressure

Congestion

MAXIMUM STRENGTH

Actual Size

NON-DROWSY

10 COATED CAPLETS* (120 mg) EACH)

*Capsule-Shaped Tablets

MAJOR® SudoGest¹²_{HOUR}
 Pseudoephedrine Hydrochloride Extended-Release Tablets USP, 120 mg
 Nasal Decongestant

NDC 0904-6754-15

COMPARE TO the active ingredient of SUDAFED®
 SINUS CONGESTION 12 HOUR CAPLETS**

MAJOR® Sinus
SudoGest¹²_{HOUR}

Pseudoephedrine Hydrochloride Extended-Release Tablets USP, 120 mg

Nasal Decongestant

- Sinus Pressure
- Congestion



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05452 5C C4

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Drug Facts (continued)

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- | | |
|---------------------------------------|---|
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**This product is not manufactured or distributed by McNeil Consumer Health care Division of McNeil-PPC, Inc., distributor of Sudafed® Sinus Congestion 12 Hour Caplets.

Distributed by: **MAJOR® PHARMACEUTICALS**
 17177 N Laurel Park Drive, Suite 233
 Livonia, MI 48152
 M-05 REV. 04/19 Re-Order No. 700962

Gluten Free





SUDOGEST 12 HOUR

pseudoephedrine hcl tablet, film coated, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0904-6754
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	120 mg

Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE	Score	no score
Shape	OVAL	Size	18mm
Flavor		Imprint Code	L054
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-6754-15	10 in 1 CARTON	02/12/2019	
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
ANDA	ANDA075153	02/12/2019	

Labeler - Major Pharmaceuticals (191427277)

Revised: 11/2022

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