

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

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**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"><li>• take 1 tablet every 12 hours</li><li>• do not take more than 2 tablets in 24 hours</li></ul>
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® SudoGest<sup>12</sup><sub>HOUR</sub>**  
 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  
**SudoGest<sup>12</sup><sub>HOUR</sub>**

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)**

**Directions**

- |                                       |   |
|---------------------------------------|---|
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**Questions or comments?** 1-800-719-9260

\*\*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:7CUC9DD19F)	PSEUDOEPHEDRINE HYDROCHLORIDE	120 mg

### Inactive Ingredients

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

### Product Characteristics

Color	WHITE	Score	no score
Shape	OVAL	Size	18 mm
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
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ANDA	ANDA075153	02/12/2019	
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**Labeler** - Major Pharmaceuticals (191427277)

Revised: 6/2019

Major Pharmaceuticals