

**PSEUDOEPHEDRINE HYDROCHLORIDE- pseudoephedrine hydrochloride tablet**  
**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.*

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**1004- Major**

***Drug Facts***

***Active ingredient (in each tablet)***

Pseudoephedrine HCl 30 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

**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 dose.**

**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.

***Directions***

- take every 4-6 hours
- do not take more than 4 doses in 24 hours

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adults & children 12 years & over	2 tablets
children 6 to under 12 years	1 tablets
children under 6 years	do not use

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**Other information**

- Store between 15° - 30°C (59° - 86°F)
- use by expiration date on package

calcium sulfate, carnauba wax, corn starch, croscarmellose sodium, FD&C red #40 lake, FD&C yellow #6 lake, gelatin, kaolin, lactose monohydrate, magnesium stearate, microcrystalline cellulose, shellac, silicon dioxide, stearic acid, sucrose, talc, titanium dioxide.

**Questions or comments?**

**1-800-616-2471**

**TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING**

Distributed by: **MAJOR® PHARMACEUTICALS**

Indianapolis, IN 46268 [www.majorpharmaceuticals.com](http://www.majorpharmaceuticals.com)

\*This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Sudafed®.

**MAJOR®**

NDC 0904-6727-60

Non Drowsy **SudoGest™**

Nasal Decongestant

Pseudoephedrine Hydrochloride 30mg

**FOR PHARMACY USE ONLY.**

**NOT FOR RETAIL SALE.**

Relieves Nasal and Sinus Congestion due to Colds or Hay Fever without drowsiness

Compare to the active ingredient in Sudafed® Sinus Congestion\*

**100 Tablets**

## Drug Facts (continued)

### Ask a doctor before use if you have

- heart disease ■ high blood pressure
- thyroid disease ■ diabetes ■ trouble urinating due to an enlarged prostate gland

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**Inactive ingredients** calcium sulfate, carnauba wax, corn starch, croscarmellose sodium, FD&C red #40 lake, FD&C yellow #6 lake, gelatin, kaolin, lactose monohydrate, magnesium stearate, microcrystalline cellulose, shellac, silicon dioxide, stearic acid, sucrose, talc, titanium dioxide.

### Questions or comments?

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**NO COPY  
ADHESIVE ZONE**

**MAJOR®**

Non-Drowsy

**Sudogest™**

**NASAL DECONGESTANT**

Pseudoephedrine Hydrochloride 30 mg

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Relieves Nasal and Sinus  
Congestion due to Colds or Hay  
Fever without drowsiness  
Compare to the active  
ingredient in  
Sudafed® Sinus Congestion\*

**100  
TABLETS**

NDC 0904-67-27-60

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**Uses** ■ temporarily relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies ■ temporarily relieves sinus congestion and pressure

### Warnings

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Rev. 08/22 M-29 Re-order No. 700918 R51444



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Lot # & Exp. Date:

PEEL  
HERE

# PSEUDOEPHEDRINE HYDROCHLORIDE

pseudoephedrine hydrochloride tablet

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0904-6727
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>PSEUDOEPHEDRINE HYDROCHLORIDE</b> (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	30 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>KAOLIN</b> (UNII: 24H4NWX5CO)	
<b>CALCIUM SULFATE ANHYDROUS</b> (UNII: E934B3V59H)	
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>SHELLAC</b> (UNII: 46N107B71O)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>SUCROSE</b> (UNII: C151H8M554)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	

## Product Characteristics

<b>Color</b>	red	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	6mm
<b>Flavor</b>		<b>Imprint Code</b>	1004
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-6727-60	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/31/2019	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	01/31/2019	

**Labeler** - Major Pharmaceuticals (191427277)

Revised: 12/2022

Major Pharmaceuticals