## SUDOGEST- pseudoephedrine hydrochloride tablet, film coated Proficient Rx LP

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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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 pregrant 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

#### Principal display panel

# FOR PHARMACY USE ONLY. NOT FOR RETAIL SALE.

NDC 63187-541-30

#### Sudo Ges t<sup>TM</sup>

#### NASAL DECONGESTANT 60 mg

Pseudoephedrine Hydrochloride 60 mg Relieves Nasal and Sinus Congestion due to Colds or Hay Fever Without Drowsiness

#### 30 TABLETS

Distributed by **MAJOR**® **PHARMACEUTICALS** 31778 Enterprise Drive Livonia, MI 48150 USA Rev. 02/13 M-17 50844 REV0712N11312

Repackaged by **Proficient Rx LP** 

Thousand Oaks, CA 91320

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





NDC 63187-541-30

Lot #:00000 Exp. 00/00/00 SN# MASTER

Sudogest 60mg (Nasal Decongestant)

#30 Tablets Lot #:00000 NDC 63187-541-30

SN#MASTER Exp:00/00/00

Sudogest 60mg (Nasal Decongestant) #30 Tablets

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Sudogest 60mg (Nasal Decongestant)

#30 Tablets Lot #:00000

Lot #:00000 NDC 63187-541-30 SN#MASTER Exp:00/00/00

Packaged By: Proficient Rx LP Thousand Oaks, CA 91320

### Sudogest 60mg (Nasal Decongestant)

#### #30 Tablets

Each tablet contains: Pseudoephedrine HCl 60mg Nasal decongestant

White, round, scored tablet with imprint code "44 113"

Product ID: PS054130

Dist. By: MAJOR PHARMACEUTICALS 31778 Enterprise Drive Livonia, MI 48150 USA
Store at 25°C (77°F)
Keep medication out of the reach of children

Major 44-113

#### **SUDOGEST**

pseudoephedrine hydrochloride tablet, film coated

Product Inform	nation
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Product TypeHUMAN OTC DRUGItem Code (Source)NDC:63187-541(NDC:0904-5125)

Route of Administration ORAL

#### **Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>PSEUDO EPHEDRINE HYDRO CHLO RIDE</b> (UNII: 6 V9 V2RYJ8 N) (PSEUDO EPHEDRINE - UNII:7CUC9 DDI9 F)	PSEUDOEPHEDRINE HYDROCHLORIDE	60 mg

Inactive Ingredients				
Ingredient Name	Strength			
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)				
LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)				

Product Characteristics			
Color	WHITE	Score	2 pieces
Shape	ROUND	Size	8 mm

Flavor	Imprint Code	44;113
Contains		

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:63187-541-15	15 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/01/2018		
2	NDC:63187-541- 30	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/0 1/20 18		
3	NDC:63187-541- 60	60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/0 1/20 18		
4	NDC:63187-541- 90	90 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/0 1/20 18		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	10/01/1994	

### Labeler - Proficient Rx LP (079196022)

Establishment			
Name	Address	ID/FEI	Business Operations
Proficient Rx LP		079196022	REPACK(63187-541), RELABEL(63187-541)

Revised: 1/2021 Proficient Rx LP