

**SUDOGEST- pseudoephedrine hcl 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.

Major 44-112

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

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 2 for 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
- diabetes
- thyroid disease
- high blood pressure
- 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 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

adults and children 12 years and older	take 2 tablets every 4 to 6 hours; do not take more than 8 tablets in 24 hours
children ages 6 to 12 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

- 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

croscarmellose sodium, dicalcium phosphate, FD&C red #40 aluminum lake, FD&C yellow #6 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, silica gel, titanium dioxide, triacetin

Questions or comments?

(800) 616-2471

Principal Display Panel

NDC 7105-133-24

*Compare to the active ingredient in Sudafed® Congestion

FOR PHARMACY USE ONLY.

NOT FOR RETAIL SALE.

Non-Drowsy

SudoGest™

NASAL DECONGESTANT

Pseudoephedrine Hydrochloride 30 mg

Relieves Nasal and Sinus Congestion due to Colds or Hay Fever Without Drowsiness

24 TABLETS

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

*This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Sudafed® Congestion.

50844 REV0712L11212

Distributed by
MAJOR® PHARMACEUTICALS
31778 Enterprise Drive
Livonia, MI 48150 USA M-17
Rev. 08/13
Re-Order No. 700321

Relabeled By;
Proficient Rx LP
Thousand Oaks CA 91320



NDC 71205-133-24

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

Sudogest 30mg (Nasal Decongestant)

#24 Tablets

Each tablet contains: Pseudoephedrine HCl 30mg
Nasal decongestant

Red, round, unscored tablet with imprint code "44 112"

Product ID: SS013324

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

Sudogest 30mg (Nasal Decongestant)
#24 Tablets Rx# MASTER
Lot #:00000 Exp:00/00/00
NDC 71205-133-24

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NDC 71205-133-24

Relabeled By: Proficient Rx LP
Thousand Oaks, CA 91320

SUDOGEST

pseudoephedrine hcl tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71205-133(NDC:0904-5053)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)
MAGNESIUM STEARATE (UNII: 70097M6I30)
POLYDEXTROSE (UNII: VH2XOU12IE)
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
TRIACETIN (UNII: XHX3C3X673)
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)
FD&C RED NO. 40 (UNII: WZB9127XOA)
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)

Product Characteristics

Color	RED	Score	no score
Shape	ROUND	Size	7mm
Flavor		Imprint Code	44;112
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71205-133-24	1 in 1 CARTON	10/01/2018	
1		24 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	08/25/1981	

Labeler - Proficient Rx LP (079196022)

Establishment

Name	Address	ID/FEI	Business Operations
Proficient Rx LP		079196022	RELABEL(71205-133)