

SUDOGEST- pseudoephedrine hydrochloride tablet
Rebel Distributors Corp

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.

SudoGest
Nasal Decongestant

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, and nasal congestion associated with sinusitis
- 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 contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

- diabetes
- thyroid disease
- heart disease
- high blood pressure
- trouble urinating due to enlargement of the prostate gland

When using this product

- do not exceed recommended dose

Stop use and ask a doctor if

- you get nervous, dizzy or sleepless
- 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 the reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away

Directions

- take every 4 to 6 hours
- do not exceed 4 doses in 24 hours

adults and children 12 years & over	2 tablets
children 6 to under 12 years	1 tablet
children under 6 years	ask a doctor

OTHER INFORMATION

- store at controlled room temperature 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

INACTIVE INGREDIENTS

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

PRINCIPAL DISPLAY PANEL

Peel	Peel	 <p style="font-size: 1.2em; font-weight: bold; margin: 0;">NDC 21695-806-12</p> <p style="font-size: 1.2em; font-weight: bold; margin: 0;">Sudogest 30mg (Nasal Decongestant)</p> <p style="font-size: 1.5em; font-weight: bold; margin: 0;">#12 Tablets Non-Drowsy</p> <p style="margin: 0;">Each tablet contains: Pseudoephedrine HCl 30mg</p> <p style="font-size: 0.8em; margin: 5px 0 0 20px;"><i>Red round tablets biconvex imprinted "TCL over 016" on one side plain on other side.</i></p> <p style="font-size: 1.2em; font-weight: bold; margin: 0;">Product ID: PS080612</p> <p style="font-size: 0.8em; margin: 0;">Dist. By: Major Pharmaceuticals 31778 Enterprise Drive, Livonia, MI 48150 USA</p>	Peel	Peel
<p>Sudogest 30mg (Nasal Decongestant): #12 Tablets Non-Drowsy Rx# Master Lot #: 000000 Exp. Date: 00/00/00 NDC 21695-806-12 AWP: \$12.94</p>	<p>Sudogest 30mg (Nasal Decongestant): #12 Tablets Non-Drowsy Rx# Master Lot #: 000000 Exp. Date: 00/00/00 NDC 21695-806-12 AWP: \$12.94</p>	<p>Lot #: 000000 Exp. 00/00/00</p>	<p>219080612 PS080612</p>	<p>Sudogest 30mg (Nasal Decongestant): #12 Tablets Non-Drowsy Rx# Master Lot #: 000000 Exp. Date: 00/00/00 NDC 21695-806-12 AWP: \$12.94</p>

Packaged by: Physician Partner, Thousand Oaks, CA 91320 www.physicianpartner.com
Store at controlled room temperature 15°-30° C (59°-86° F) Keep medication out of the reach of children.

SUDOGEST			
pseudoephedrine hydrochloride tablet			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21695-806(NDC:0904-5053)
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	Pseudoephedrine Hydrochloride (UNII: 6 V9 V2RYJ8N) (Pseudoephedrine - UNII:7CUC9DDI9F)	Pseudoephedrine Hydrochloride	30 mg
Inactive Ingredients			
	Ingredient Name	Strength	
	Croscarmellose Sodium (UNII: M28OL1HH48)		
	FD&C YELLOW NO. 6 (UNII: H77VEI93A8)		
	HYPROMELLOSES (UNII: 3NXW29V3WO)		
	Magnesium Stearate (UNII: 70097M6I30)		
	Polydextrose (UNII: VH2XOU12IE)		

POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)

Titanium Dioxide (UNII: 15FIX9V2JP)

Triacetin (UNII: XHX3C3X673)

Product Characteristics

Color	RED	Score	no score
Shape	ROUND	Size	7mm
Flavor		Imprint Code	44112
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21695-806-12	12 in 1 BLISTER PACK		

Marketing Information

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

Labeler - Rebel Distributors Corp (118802834)

Establishment

Name	Address	ID/FEI	Business Operations
Rebel Distributors Corp		118802834	RELABEL, REPACK

Revised: 3/2012

Rebel Distributors Corp