

PSEUDO-TIME - pseudoephedrine hcl tablet, coated
TIME CAP LABORATORIES, INC.

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.

In each tablet Pseudoephedrine HCl 30 mg

Nasal Decongestant

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away

INDICATIONS AND USAGE:

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 drug contains an MAOI, ask a doctor or pharmacist before taking this product.

DOSAGE AND ADMINISTRATION:

Directions – take every 4-6 hours -Do not take more than 4 does in 24 hours

Adults and children 12 years and over – 2 tablets

Children 6 to under 12 years – 1 tablet

Children under 6 years – ask a doctor

INACTIVE INGREDIENTS: acacia, calcium sulfate, carnauba Wax, colloidal silicon dioxide, corn starch, D-C red no. 27, D-C yellow no.10, FD-C red no.40, FD-C yellow no 6, iron oxide black, iron oxide red, iron oxide yellow (iron oxide ochre) Kaolin, microcrystalline cellulose, polyethylene glycol (PEG) 400, , pregelatinized starch, sodium starch glycolate, stearic acid, sugar, talc, titanium dioxide



Non-Drowsy PSEUDO-TIME

Pseudoephedrine HCl 30 mg

96 Tablets

NDC 49483-016-96



Non-Drowsy
PSEUDO-TIME
Pseudoephedrine HCl 30 mg
96 Tablets



Non-Drowsy PSEUDO-TIME

Pseudoephedrine HCl 30 mg

**MAXIMUM STRENGTH
NASAL DECONGESTANT**

Relieves Nasal & Sinus Congestion
due to Colds and Allergies

*Compare to the active ingredient in Sudafed® Nasal Decongestant

RETAIN CARTON FOR COMPLETE PRODUCT INFORMATION

Drug Facts		Drug Facts (continued)	
Active ingredient (in each tablet) Pseudoephedrine HCl 30 mg	Purpose Nasal Decongestant	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.	
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.		Directions Take every 4-6 hours. Do not take more than 4 doses in 24 hours. Adults and children 12 years and over: 2 tablets Children 6 to under 12 years: 1 tablet Children under 6 years: ask a doctor	
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, thyroid disease, trouble urinating due to an enlarged prostate gland, high blood pressure, diabetes. When using this product: do not use more than directed. Stop use and ask a doctor if: symptoms do not improve within 7 days or are accompanied by fever, you get nervous, dizzy or sleepless.		Other information TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING. Store at room temperature 15°-30° (59°-86°F) in a dry place. Protect from light.	
		Inactive ingredients acacia, beeswax, calcium sulfate, carnauba wax, croscollon, silicon dioxide, corn starch, D&C red #27, D&C yellow #10, FD&C red #40, FD&C yellow #6, hydroxypropylmethylcellulose, pharmaceutical glaze, pregelatinized starch, sodium starch glycolate, stearic acid, sugar, talc, titanium dioxide.	



This product is not manufactured or distributed by Warner-Lambert Consumer Healthcare, owners of the registered trademark Sudafed® Nasal Decongestant.
29R 0304
Manufactured by Time-Cap Labs, Inc. Farmingdale, NY 11735

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PSEUDO-TIME

pseudoephedrine hcl tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49483-016
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
ACACIA (UNII: 5C5403N26O)	
CALCIUM SULFATE ANHYDROUS (UNII: E934B3V59H)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
KAOLIN (UNII: 24H4NWX5CO)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	red	Score	no score
Shape	ROUND	Size	6mm
Flavor		Imprint Code	TCL016
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49483-016-96	96 in 1 BLISTER PACK		

2	NDC:49483-016-24	24 in 1 BLISTER PACK		
3	NDC:49483-016-48	48 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	05/01/2012	

Labeler - TIME CAP LABORATORIES, INC. (037052099)

Establishment

Name	Address	ID/FEI	Business Operations
TIME CAP LABORATORIES, INC.		037052099	manufacture(49483-016)

Revised: 7/2012

TIME CAP LABORATORIES, INC.