

PSEUDO TIME PE- phenylephrine hchloride tablet, film 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.

49483-234 pseudo time pe

Each tablet contains: Phenylephrine HCl 10 mg

INACTIVE INGREDIENTS: CARNAUBA WAX, CROSCARMELLOSE SODIUM, DIBASIC CALCIUM PHOSPHATE DIHYDRATE, FD-C RED#40 ALUMINUM LAKE, FD-C YELLOW#6 ALUMINUM LAKE, HYPROMELLOSE, MAGNESIUM STEARATE, MICROCRYSTALLINE CELLULOSE, POLYETHYLENE GLYCOL (PEG) 400, STEARIC ACID, TITANIUM DIOXIDE

keep out of the reach of children. In case of overdose, get medical help or contact a Poison Control Center immediately.

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

DIRECTIONS:

Take every 4 hours; Do not take more than 6 doses in 24 hours; Adults and children 12 years of age and over; 1 tablet
Children under 12 years of age; ask a doctor

WARNINGS;

Do not use if you are 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.



Maximum Strength
Non-Drowsy
PSEUDO-TIME PE
 Phenyneprhine HCl 10 mg

NDC-49483-234-18

Does not contain Pseudoephedrine



Maximum Strength

Non-Drowsy PSEUDO-TIME PE
 Phenyneprhine HCl 10 mg
 18 Tablets
Maximum Strength

18 Tablets

Non-Drowsy PSEUDO-TIME PE
NASAL DECONGESTANT
 Phenyneprhine HCl 10 mg
 Relieves
 • Nasal & Sinus Congestion
 • Sinus Pressure
 *Compare to the active ingredient in Sudafed PE™.

RETAIN CARTON FOR COMPLETE PRODUCT INFORMATION

<p>Drug Facts</p> <p>Active ingredient (in each tablet) Phenyneprhine HCl 10 mg</p> <p>Purpose Nasal decongestant</p> <p>Uses</p> <ul style="list-style-type: none"> temporarily relieves nasal congestion due to the common cold, hay fever, or other non-infectious respiratory allergies and nasal congestion associated with sinusitis temporarily relieves sinus congestion and pressure <p>Warnings</p> <p>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.</p> <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> heart disease high blood pressure diabetes thyroid disease difficulty in urination due to enlargement of the prostate gland <p>When using this product do not exceed recommended dosage</p> <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> you get nervous, dizzy or sleepless 	<p>Drug Facts (continued)</p> <ul style="list-style-type: none"> symptoms do not improve within 7 days or are accompanied by 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 immediately. <p>Directions</p> <ul style="list-style-type: none"> take every 4 hours do not take more than 6 doses in 24 hours adults and children 12 years of age and over: 1 tablet children under 12 years of age: ask a doctor <p>Other Information</p> <ul style="list-style-type: none"> TAMPER EVIDENT: EACH TABLET IS SAFETY SEALED. DO NOT USE IF BUSTER OR PULL IS BROKEN OR SHOWS ANY SIGNS OF TAMPERING store at room temperature 15°-30° (59°-86°F) in a dry place protect from light <p>Inactive ingredients carmelum wax, croscarmellose sodium, dicalcium phosphate, FD&C red #40, FD&C yellow #6, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol (PEG)-400, stearic acid, titanium dioxide</p>
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Pharmingdiate, NY 11735
 TIME-CAP PARS, INC.
 Manufactured by
 234-18 PSE
 234-18 PSE
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 Consumer information not to be printed on product packaging. For more information, visit us at www.time-cap.com

PSEUDO TIME PE
 phenylephrine hchloride tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49483-234
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg

Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM SILICATE (UNII: 9B9691B2N9)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	red	Score	no score
Shape	ROUND	Size	7mm
Flavor		Imprint Code	T234
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49483-234-18	18 in 1 BLISTER PACK; Type 0: Not a Combination Product	12/14/2018	
2	NDC:49483-234-36	36 in 1 BLISTER PACK; Type 0: Not a Combination Product	12/14/2018	
3	NDC:49483-234-00	100000 in 1 CARTON; Type 0: Not a Combination Product	12/14/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	05/14/2012	

Labeler - TIME CAP LABORATORIES, INC. (037052099)

Establishment

Name	Address	ID/FEI	Business Operations
TIME CAP LABORATORIES, INC		037052099	manufacture(49483-234)

Revised: 12/2018

TIME CAP LABORATORIES, INC.