

SINUS CONGESTION PE- phenylephrine hydrochloride tablet, coated
AMERIFOODS TRADING COMPANY

1131-FIR-2023-1102

Drug Facts

Active ingredient (in each tablet)

Phenylephrine HCl 10 mg

Purpose

Nasal decongestant

Uses

- temporarily relieves sinus congestion and pressure
- temporarily relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies

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
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland

When using this product

do not exceed recommended dosage

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- symptoms do not improve within 7 days or occur with a 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 (1-800-222-1222).

Directions

- adults and children 12 years of age and over: take 1 tablet every 4 hours; do not take more than 6 tablets in 24 hours
- children under 12 years of age: ask a doctor

Other information

- store between 20-25°C (68-77°F) in a dry place
- retain carton for complete product information and warnings

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, D&C red #27 aluminum lake, FD&C red #40 aluminum lake, FD&C yellow #6 aluminum lake, hypromellose, lactose anhydrous, magnesium stearate, polyethylene glycol, stearic acid, titanium dioxide

Questions or comments?

1-844-705-4384

PRINCIPAL DISPLAY PANEL

First Street®

NDC 61504-131-03

†COMPARE TO THE ACTIVE INGREDIENT IN SUDAFED PE® SINUS CONGESTION

MAXIMUM STRENGTH

Sinus Congestion PE

Phenylephrine HCl Tablets

Nasal Decongestant

For Relief of:

Sinus Pressure

Sinus Congestion

NON-DROWSY

ACTUAL SIZE

36 TABLETS • 10 mg EACH



MAXIMUM STRENGTH

Sinus Congestion PE

Phenylephrine HCl Tablets

Nasal Decongestant

11/16



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FS2308



MAXIMUM STRENGTH

Sinus Congestion PE

Phenylephrine HCl Tablets

Nasal Decongestant

NDC 61504-131-03

*COMPARE TO THE ACTIVE INGREDIENT
IN SUDAFED PE® SINUS CONGESTION

For Relief of:

Sinus Pressure
Sinus Congestion



NON-DROWSY

ACTUAL SIZE

36 TABLETS • 10 mg EACH

NC

11/16

8/9

NC

Drug Facts (continued)	
Purpose Phenylephrine HCl 10 mg.....Nasal decongestant	
Uses ■ temporarily relieves sinus congestion and pressure ■ temporarily relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies	
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 ■ high blood pressure ■ thyroid disease ■ diabetes ■ trouble urinating due to an enlarged prostate gland	
When using this product do not exceed recommended dosage ■ nervousness, dizziness, or sleeplessness occur ■ symptoms do not improve within 7 days or occur with a fever If pregnant or breast-feeding, ask a health professional before use.	
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Inactive ingredients croscarmellose sodium, D&C red #27 aluminum lake, FD&C red #40 aluminum lake, FD&C yellow #6 aluminum lake, hypromellose, lactose anhydrous, magnesium stearate, polyethylene glycol, stearic acid, titanium dioxide	
Questions or comments? 1-844-705-4384	

Directions	
adults and children 12 years and over	■ take 1 tablet every 4 hours ■ do not take more than 6 tablets in 24 hours
children under 12 years	■ ask a doctor

DO NOT USE IF BLISTER UNITS ARE TORN OR BROKEN

100% SATISFACTION GUARANTEED OR YOUR MONEY BACK

*This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Sudafed PE® Sinus Congestion.

DISTRIBUTED BY:
AMERIFOODS TRADING CO.
P.O. BOX 512377
LOS ANGELES, CA 90051-0377

SINUS CONGESTION PE

phenylephrine hydrochloride tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61504-131
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
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	red	Score	no score
Shape	ROUND	Size	7mm
Flavor		Imprint Code	A;131
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61504-131-03	2 in 1 CARTON	10/30/2023	
1		18 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
OTC Monograph Drug	M012	10/30/2023	

Labeler - AMERIFOODS TRADING COMPANY (626388680)

Revised: 11/2023

AMERIFOODS TRADING COMPANY