CONGESTION PE- phenylephrine hydrochloride tablet, coated Harris Teeter

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.

HTE - 1131 - 2019-1010

Drug Facts

Active ingredient (in each tablet)

Phenylephrine HCl 10 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 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 use more than directed

Stop use and ask a doctor if

- you get nervous, dizzy, or sleepless
- 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 reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

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 at 15°-25°C (59°-77°F) in a dry place
- retain carton for complete product information

Inactive ingredients

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

PRINCIPAL DISPLAY PANEL

Harris Teeter

Congestion PE

Compare to the Active Ingredient in Sudafed(R) PE Congestion

Maximum Strenght, Non-Drowsy

Phenylephrine HCl, 10 mg

NASAL DECONGESTANT

Relieves

Sinus Pressure

Sins Congestion

18 Tablets

■ symptoms do not improve within 7 days or are accompanied ■ you get nervous, dizzy, or sleepless Stop use and ask a doctor if

When using this product a do not use more than directed

- trouble urinating due to an enlarged prostate gland
 - diabetes ■ thyroid disease
 - high blood pressure ■ heart disease Ask a doctor before use if you have

pharmacist before taking this product. your prescription drug contains an MAOI, ask a doctor or for 2 weeks after stopping the MAOI drug. If you do not know if psychiatric, or emotional conditions, or Parkinson's disease), or oxidase inhibitor (MAOI) (certain drugs for depression, Do not use if you are now taking a prescription monoamine **SprinseW**

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

Nasal decongestant Purpose

Phenylephrine HCl 10 mg. Active ingredient (in each tablet)

Drug Facts

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

every 4 hours; do not take more than 6 tablets in 24 hours

adults and children 12 years of age and over: take 1 tablet

stesrate, polyethylene glycol, stearic acid, titanium dioxide

croscarmellose sodium, D&C red #27, FD&C red #40, FD&C

yellow #6, hypromellose, lactose anhydrous, magnesium

Inactive ingredients colloidal silicon dioxide,

retain carton for complete product information

■ children under 12 years of age: ask a doctor

■ store at 15°-25°C (59°-77°F) in a dry place

If pregnant or breast-feeding, ask a health professional

Drug Facts (continued)

1-800-432-6111 or harristeeter.com your**plus**guarantee.

MATTHEWS, NC 28105

PROUDLY DISTRIBUTED BY:

HARRIS TEETER, INC.

Other information

Directions



Congestion PE

Maximum Strength, Non-Drowsy · Phenylephrine HCI, 10 mg





Harris Teeter

†Compare to the

Active Ingredient in Sudafed® PE Congestion

Congestion PE

Maximum Strength, Non-Drowsy Phenylephrine HCI, 10 mg

NASAL DECONGESTANT

Relieves

- Sinus Pressure
- Sinus Congestion

18 Tablets



Congestion PE

Maximum Strength, Non-Drowsy · Phenylephrine HCI, 10 mg

F113102HTE_R0

USE IF BLISTER UNITS TORN OR BROKEN NOT (

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

phenylephrine hydrochloride tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72036-131
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
PHENYLEPHRINE HYDRO CHLO RIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg	

Inactive Ingredients	
Ingredient Name	Strength
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
ANHYDROUS LACTOSE (UNII: 3S Y5LH9 PMK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	

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:72036-131-02	1 in 1 CARTON	06/11/2013		
1		18 in 1 BLISTER PACK; Type 0: Not a Combination Product			
2	NDC:72036-131-03	2 in 1 CARTON	06/11/2013		
2		18 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	06/11/2013		

Labeler - Harris Teeter (047279351)

Revised: 10/2019 Harris Teeter