# NASAL DECONGESTANT PE- phenylephrine hydrochloride tablet, coated VALU MERCHANDISERS COMPANY

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.

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1131-BST-2021-1117

**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

COMPARE TO THE ACTIVE INGREDIENT IN SUDAFED PE® CONGESTION†

Best Choice®

Non-Drowsy

MAXIMUM STRENGTH

NASAL DECONGESTANT PE

**Actual Size** 

Phenylephrine HCl

For Relief of:

- Sinus Pressure
- Congestion

18 TABLETS

10 mg EACH

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    - high blood pressure ■ heart disease

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- temporarily 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 HCI 10 mg. Active ingredient (in each tablet)

Drug Facts

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Drug Facts (continued)

Non-Drowsy

**MAXIMUM STRENGTH** 

**NASAL DECONGESTANT PE** 

Best Choice®





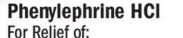
COMPARETO THE ACTIVE INGREDIENT IN SUDAFED PE® CONGESTION

Non-Drowsy

**MAXIMUM STRENGTH** 

**NASAL DECONGESTANT PE** 

**Actual Size** 



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Best Choice

Non-Drowsy **MAXIMUM STRENGTH NASAL DECONGESTANT PE** 

USE IF BLISTER UNITS TORN OR BROKEN DO NOT U

### **NASAL DECONGESTANT PE**

phenylephrine hydrochloride tablet, coated

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Pro	duct	Inform	ation

**Route of Administration** ORAL

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

Inactive Ingredients		
Ingredient Name	Strength	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)		
<b>D&amp;C RED NO. 27</b> (UNII: 2LRS185U6K)		
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)		

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:63941- 331-02	1 in 1 PACKAGE	03/15/2017	
1		18 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:63941- 331-03	2 in 1 CARTON	03/07/2017	
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	03/07/2017		

# Labeler - VALU MERCHANDISERS COMPANY (868703513)

Revised: 11/2021 VALU MERCHANDISERS COMPANY