

NASAL DECONGESTANT PE- phenylephrine hydrochloride tablet
The Kroger Co.

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.

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
- 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

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

When using this product,

do not exceed recommended dose.

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 and over: take 1 tablet every 4 hours. Do not take more than 6 tablets in 24 hours.
- children under 12 years: do not use this product for children under 12 years of age

Other information

- store at 20°-25°C (68°-77°F)

Inactive ingredients

carnauba wax, croscarmellose sodium, dibasic calcium phosphate dihydrate, FD&C red #40 aluminium lake, FD&C yellow #6 aluminium lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol (PEG) 400, stearic acid, titanium dioxide

Questions or comments?

1-800-632-6900

Principal Display Panel

Compare to the active ingredient of SUDAFED PE® NASAL DECONGESTANT *See bottom panel

NON- DROWSY

Nasal Decongestant PE

Phenylephrine HCl Tablets

Nasal Decongestant

Does Not Contain Pseudoephedrine

MAXIMUM STRENGTH

Relieves:

- Nasal & Sinus Congestion
- Sinus Pressure

1 pill/dose

TABLETS 10 mg EACH

GLUTEN FREE

***Sudafed PE® is a registered trademark of McNeil Consumer Healthcare, Fort Washington, PA 19034. McNeil Consumer Healthcare is not affiliated with The Kroger Co. or this product.**

EACH DOSE INDIVIDUALLY SEALED IN A BLISTER PACK . DO NOT USE IF BLISTER UNIT IS TORN OR BROKEN.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

V60X4



Drug Facts
Active ingredient (in each tablet) Phenylephrine HCl 10 mg.....Nasal decongestant

Uses
 ■ temporarily relieves nasal congestion due to the common cold, hay fever, or other upper respiratory allergies
 ■ 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 ■ high blood pressure ■ heart disease ■ thyroid disease ■ diabetes ■ trouble urinating due to an enlarged prostate gland.

When using this product, do not exceed recommended dose.
Stop use and ask a doctor if
 ■ symptoms do not improve within 7 days or occur with a fever
 ■ nervousness, dizziness, or sleeplessness occur

Drug Facts (continued)
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 and over: take 1 tablet every 4 hours. Do not take more than 6 tablets in 24 hours.
 ■ children under 12 years: do not use this product for children under 12 years of age

Other information
 ■ store at 20°-25°C (68°-77°F)

Inactive ingredients camaruba wax, croscarmellose sodium, dibasic calcium phosphate dihydrate, FD&C red #40 aluminum lake, FD&C yellow #6 aluminum lake, hypromellose, magnesium stearate, titanium dioxide, microcrystalline cellulose, polyethylene glycol (PEG) 400, stearic acid.

Questions or comments?
 1-800-632-6900



NON-DROWSY
Nasal Decongestant PE
 Phenylephrine HCl Tablets, Nasal Decongestant

COMPARE TO the active ingredient of **SUDAFED PE® NASAL DECONGESTANT**
 *See bottom panel

NDC 30142-670-18



NON-DROWSY
Nasal Decongestant PE
 Phenylephrine HCl Tablets
Nasal Decongestant

Does Not Contain Pseudoephedrine

MAXIMUM STRENGTH

- Relieves:
- Nasal & Sinus Congestion
 - Sinus Pressure

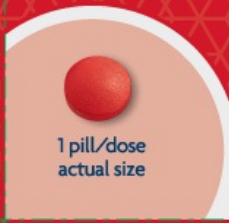


18
TABLETS
10 mg EACH

Lot No.:
 Exp. Date:

EACH DOSE INDIVIDUALLY SEALED IN A BLISTER PACK.
 DO NOT USE IF BLISTER UNIT IS TORN OR BROKEN.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.



1 pill/dose actual size

DISTRIBUTED BY THE KROGER CO.
 CINCINNATI, OHIO 45202

QUALITY GUARANTEE
www.kroger.com

GLUTEN FREE
 PLD-C
 FC001903



*SUDAFED PE® IS A REGISTERED TRADEMARK OF MCNEIL CONSUMER HEALTHCARE, FORT WASHINGTON, PA 19034. MCNEIL CONSUMER HEALTHCARE IS NOT AFFILIATED WITH THE KROGER CO. OR THIS PRODUCT.

Kroger Nasal Decongestant PE Tablets

NASAL DECONGESTANT PE
 phenylephrine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:30 142-670
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)	
CALCIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: O7TSZ97GEP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6B30)	
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:30 142-670-18	1 in 1 CARTON		
1		18 in 1 BLISTER PACK		
2	NDC:30 142-670-36	2 in 1 CARTON		
2		18 in 1 BLISTER PACK		
3	NDC:30 142-670-72	4 in 1 CARTON		
3		18 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	02/02/2011	

