

NASAL DECONGESTANT PE MAXIMUM STRENGTH- phenylephrine hydrochloride tablet Preferred Plus (Kinray)

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 occurs
- 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.

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?

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

Principal Display Panel

*Compare to active ingredient in Sudafed PE®

MAXIMUM STRENGTH

Without Drowsiness

Nasal Decongestant PE

Phenylephrine HCl tablets • Nasal decongestant

Does not contain Pseudoephedrine

For the Relief of:

- Nasal and Sinus Congestion
- Sinus Pressure

Tablets 10 mg Each

*This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Sudafed PE®.

Distributed by Kinray, LLC.

152-35 Tenth Avenue

Whitestone, NY 11357.

TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

Product Label

Drug Facts	Active ingredient (in each tablet) Phenylephrine HCl 10 mg.....Nasal decongestant
Uses	<ul style="list-style-type: none"> temporarily relieves nasal congestion due to the common cold, hay fever, or other upper respiratory allergies temporarily relieves sinus congestion and pressure
Warnings	<ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> high blood pressure heart disease thyroid disease diabetes trouble urinating due to an enlarged prostate gland
Stop use and ask a doctor if	<ul style="list-style-type: none"> nervousness, dizziness, or sleeplessness occur symptoms do not improve within 7 days or occur with a fever
When using this product, do not exceed recommended dose.	
Questions or comments?	Call 1-877-753-3935 Monday-Friday 9AM-5PM EST
Other information	store at 20°-25°C (68°-77°F)
Inactive ingredients	carbamab 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
Directions	<ul style="list-style-type: none"> 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
Drug Facts (continued)	<ul style="list-style-type: none"> 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.

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Preferred Plus Pharmacy
MAXIMUM STRENGTH Nasal Decongestant PE 18 Tablets
 Phenylephrine HCl tablets • Nasal decongestant **10 mg Each**

NDC 61715-044-18

*Compare to active ingredient in Sudafed PE®
 Without Drowsiness

Preferred Plus Pharmacy
MAXIMUM STRENGTH Nasal Decongestant PE
 Phenylephrine HCl tablets • Nasal decongestant

Does not contain Pseudoephedrine

For the Relief of:

- Nasal and Sinus Congestion
- Sinus Pressure

18 Tablets 10 mg Each



PLD-D
 FC001894
 Lot No.:
 Exp. Date:

Distributed by: Kinray, LLC.
 152-35 Tenth Avenue
 Whitestone, NY 11357.

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KIN# 899-542



Preferred Plus Nasal Decongestant PE Tablet

NASAL DECONGESTANT PE MAXIMUM STRENGTH

phenylephrine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61715-044	
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)				
CROSCARMELOSE 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: 70097M6I30)				
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)				
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
ALUMINUM OXIDE (UNII: LM26O6933)				
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:61715-044-18	1 in 1 CARTON	07/07/2010	12/31/2020
1		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	07/07/2010	12/31/2020	

Labeler - Preferred Plus (Kinray) (012574513)