

NASAL DECONGESTANT PE- phenylephrine hydrochloride tablet
HHH PHARMA USA LLC

Active Ingredient (in each caplet)

Phenylephrine HCl 10mg

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

- heart disease
- high blood pressure
- 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 (1-800 222-1222) 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:** ask a doctor

Other Information

- each tablet contains: phosphorus 10 mg
- store at controlled room temperature between 20°-25°C (68°-77°F)
- protect from excessive moisture
- read all product information before using

Inactive Ingredients

Crosscarmellose Soidum, Colloidal Silicon Dioxide, Dicalcium Phosphate, FD&C Red 40, Magnesium Stearate, Microcrystalline Cellulose

Questions or comments?

Call + 1-848-235-5293

Monday through Friday 9AM – 4PM EST

PRINCIPAL DISPLAY PANEL

Drug Facts (Continued)

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NDC 83586-160-01

Compare to the active ingredient in Sudafed PE® Sinus Congestion*

NON-DROWSY

NASAL DECONGESTANT PE

Phenylephrine 10 mg

Relieves:
 Nasal, Sinus Congestion &
 Sinus Pressure

100 Tablets

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DRUG FACTS CONTINUED on back of the label ▶

TAMPER EVIDENCE: DO NOT USE IF SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

*This product is not manufactured or distributed by the owner of the registered trademark Sudafed PE® Sinus Congestion.
 Distributed by: HHH Pharma USA LLC, Rahway, NJ 07065
 www.hhhpharma.com

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PEEL HERE ▶

NASAL DECONGESTANT PE

phenylephrine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83586-160
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)		PHENYLEPHRINE	10 mg

Inactive Ingredients				
Ingredient Name				Strength
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
DICALCIUM PHOSPHATE (UNII: L11K75P92J)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
Product Characteristics				
Color	red	Score	no score	
Shape	ROUND	Size	7mm	
Flavor		Imprint Code	S08	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83586-160-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	07/28/2025	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012		07/28/2025	

Labeler - HHH PHARMA USA LLC (062788820)

Registrant - HHH PHARMA USA LLC (062788820)

Establishment			
Name	Address	ID/FEI	Business Operations
Elysium Pharmaceuticals Ltd		863182240	manufacture(83586-160)

Establishment			
Name	Address	ID/FEI	Business Operations
HHH PHARMA USA LLC		062788820	pack(83586-160)