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

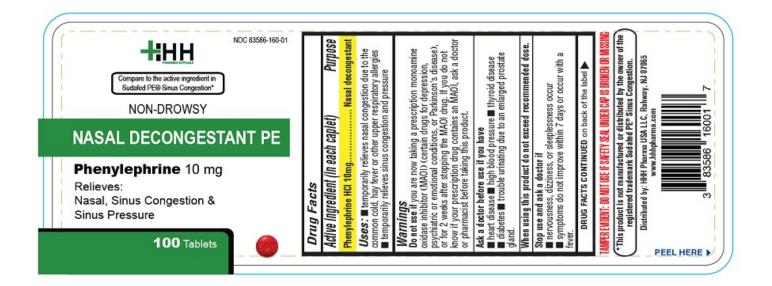
Questions or comments?

Call + 1-848-235-5293

Monday through Friday 9AM - 4PM EST

PRINCIPAL DISPLAY PANEL





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: 1WS 297W6MV)	PHENYLEPHRINE	10 mg	

Inactive Ingredients			
Ingredient Name	Strength		
CROSCARMELLOSE 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			

ı	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)

Revised: 7/2025 HHH PHARMA USA LLC