

NON-DROWSY NASAL DECONGESTANT PE- phenylephrine hcl tablet, film coated
Strive Pharmaceuticals Inc.

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.

Non-Drowsy Nasal Decongestant
Phenylephrine Hydrochloride Tablets 10mg

Phenylephrine HCl 10mg

microcrystalline cellulose, dibasic calcium phosphate, croscarmellose sodium, stearic acid, magnesium stearate, polyvinyl alcohol, polyethylene glycol, talc, FD&C yellow# 6, FD&C red #40, titanium dioxide, D&C yellow #10

* take with a full glass of water

* swallow whole; do not crush, chew or dissolve

adults and children 12 years and over	<ul style="list-style-type: none">• 1 tablet every 4 hours• Do not take more than 6 tablets in 24 hours
children under 12 years	Ask a doctor

* temporarily relieves sinus congestion and pressure

* temporarily relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies

*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
- diabetes
- thyroid disease
- 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 accidental overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

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Nasal Decongestant

Drug Facts (continued)

Drug Facts (continued)

Other information

■ Store between 20°-25°C (68°-77°) excursions permitted between 15°-30°C (59°-86°F)

TAMPER EVIDENT: Do not use if package is opened or if blister unit is torn, broken or shows any signs of tampering.

Inactive ingredients

croscarmellose sodium, D&C yellow #10 aluminum lake, dibasic calcium phosphate, FD&C red #40 aluminum lake, FD&C yellow #6 aluminum lake, hypromellose, lactose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, silicon dioxide, stearic acid, talc, titanium dioxide, may contain.

Questions or comments?

Call 1 (888) 577-8033

Drug Facts

Active ingredient (in each tablet)

Phenylephrine HCl 10mg

Purpose

Nasal Decongestant

Directions

Take with a full glass of water

swallow whole; do not crush, chew or dissolve

Uses

temporarily relieves: nasal congestion due to the common cold, hay fever, or other upper respiratory allergies ■ nasal congestion associated with sinusitis ■ 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 ■ diabetes ■ thyroid disease ■ 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.

OVERDOSE WARNING: In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as children even if you do not notice any signs or symptoms.

Nasal Decongestant PE

nasal & sinus congestion
sinus pressure

MAXIMUM STRENGTH phenylephrine hydrochloride
10 mg each tablet

24
tablets

NON-DROWSY

Nasal Decongestant PE

nasal & sinus congestion
sinus pressure

MAXIMUM STRENGTH phenylephrine hydrochloride
10 mg each tablet

24
tablets

†compare to active ingredient in
Sudafed PE® Congestion

NDC 70692-100-24

Lot. No. _____ Exp. Date: _____

Distributed by:
STRIVE PHARMACEUTICALS INC.
East Brunswick, NJ 08816
CT 70692-10024
REV. 01-01-2020

READ AND KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

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

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FREE AREA COATING

NON-DROWSY NASAL DECONGESTANT PE

phenylephrine hcl tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70692-100
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
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL 1000000 (UNII: HZ58M6D839)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	red	Score	no score
Shape	ROUND	Size	7mm
Flavor		Imprint Code	S71
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70692-100-24	24 in 1 BLISTER PACK; Type 0: Not a Combination Product	02/22/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	02/22/2018	

