

CARE ONE NASAL DECONGESTANT PE MAXIMUM STRENGTH NON DROWSY-phenylephrine hydrochloride tablet, film coated

American Sales Company

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.

American Sales Company Nasal Decongestant PE Drug Facts

Active ingredient (in each tablet)

Phenylephrine HCl 10 mg

Purpose

Nasal decongestant

Uses

- temporarily relieves sinus congestion and pressure
- temporarily relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies

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 dosage

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	<ul style="list-style-type: none">• 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

- store at 20-25°C (68-77°F)
- do not use if blister unit is broken or torn

Inactive ingredients

anhydrous dibasic calcium phosphate, carnauba wax, FD&C red no. 40 aluminum lake, lecithin, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, silicon dioxide, talc, titanium dioxide

Questions or comments?

1-800-719-9260

Principal Display Panel

Compare to the active ingredient in Sudafed PE® Congestion

NASAL DECONGESTANT PE

Phenylephrine HCl Tablets

Nasal Decongestant

Maximum Strength

Relieves:

Nasal & Sinus Congestion

Sinus Pressure

Non-Drowsy

Gluten Free

Actual Size

OUR PHARMACISTS RECOMMEND

72 TABLETS

10 mg EACH



CAREone®

NDC 41520-094-23

Compare to the active ingredient in
Sudafed PE® Congestion*

NASAL DECONGESTANT PE

Phenylephrine HCl Tablets
Nasal Decongestant

Maximum Strength

Relieves:

- Nasal & Sinus Congestion
- Sinus Pressure

Non-Drowsy

Gluten Free



Actual Size



72 TABLETS
10 mg EACH





: 09423 0F 03

Important: Read all product information before using. Keep this box for important information.

Drug Facts

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

Uses

- temporarily relieves sinus congestion and pressure
- temporarily relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies

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 dosage

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).

Drug Facts (continued)

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

- store at 20-25°C (68-77°F)
- do not use if blister unit is broken or torn

Inactive ingredients anhydrous dibasic calcium phosphate, carnauba wax, FD&C red no. 40 aluminum lake, lecithin, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, silicon dioxide, talc, titanium dioxide

Questions or comments? 1-800-719-9260

*This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Sudafed PE® Congestion.

DISTRIBUTED BY FOODHOLD U.S.A., LLC
LANDOVER, MD 20785 · 1-877-846-9949
©2017 S&S Brands, LLC

Quality guaranteed or your money back.

OPEN OTHER END

CONVENIENT RECLOSING TAB



CARE ONE NASAL DECONGESTANT PE MAXIMUM STRENGTH NON DROWSY

phenylephrine hydrochloride tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-094
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)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	

MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

Product Characteristics

Color	RED	Score	no score
Shape	ROUND	Size	8mm
Flavor		Imprint Code	L7
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-094-23	72 in 1 CARTON	10/09/2017	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:41520-094-68	36 in 1 CARTON	11/20/2009	11/20/2011
2		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:41520-094-89	18 in 1 CARTON	08/22/2017	
3		1 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	05/17/2005	

Labeler - American Sales Company (809183973)

Revised: 12/2019

American Sales Company