TOPCARE NASAL DECONGESTANT PE- phenylephrine hydrochloride tablet, film coated
Topco Associates LLC

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.

Topco Associates LLC. 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	• 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?

1-888-423-0139

Principal Display Panel

COMPARE TO SUDAFED PE® CONGESTION

ACTIVE INGREDIENT

NON-DROWSY

Nasal Decongestant PE

PHENYLEPHRINE HCl TABLETS, 10 mg

MAXIMUM STRENGTH

OUR PHARMACISTS RECOMMEND

Sinus + Nasal Congestion

Sinus Pressure

actual size

72 TABLETS

TopCare® health™

Nasal Decongestant PE

PHENYLEPHRINE HCl TABLETS, 10 mg

MAXIMUM STRENGTH

SUSTAINABLE FORESTRY INITIATIVE
Certified Sourcing
www.sfiprogram.org
SFI-01052

TopCare® health™

NDC 36800-094-23

COMPARE TO SUDAFED PE® CONGESTION ACTIVE INGREDIENT*

NON-DROWSY

Nasal Decongestant PE

PHENYLEPHRINE HCl TABLETS, 10 mg

MAXIMUM STRENGTH

OUR PHARMACISTS RECOMMEND

- Sinus + Nasal Congestion
- Sinus Pressure

72 TABLETS

actual size

OPEN OTHER END

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

Drug Facts

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Drug Facts (continued)

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©TOPCO PER1017 QUESTIONS? 1-888-423-0139
topcare@topco.com www.topcarebrand.com

GF GLUTEN FREE

CONVENIENT RECLOSING TAB

QUALITY GUARANTEED

This Top Care® product is laboratory tested to guarantee its highest quality. Your total satisfaction is guaranteed.

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

TOPCARE NASAL DECONGESTANT PE

phenylephrine hydrochloride tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:36800-094
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, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (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:36800-094-23	12 in 1 CARTON	09/19/2005	01/31/2022
1		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:36800-094-47	1 in 1 CARTON	02/03/2009	07/02/2011
2		150 in 1 BOTTLE; Type 0: Not a Combination Product		

3	NDC:36800-094-68	6 in 1 CARTON	09/13/2005	
3		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:36800-094-89	3 in 1 CARTON	09/12/2005	
4		6 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	09/12/2005	

Labeler - Topco Associates LLC (006935977)

Revised: 11/2021 Topco Associates LLC