CARING MILL SINUS PE- phenylephrine hydrochloride tablet, film coated FSA Store 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.

FSA Store Inc. Sinus 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?

1-800-719-9260

Principal Display Panel

caring mill™

Compare to the active ingredient of Sudafed PE® Congestion

Non-Drowsy • Maximum Strength

Sinus PE

Nasal Decongestant

Phenylephrine HCl, 10 mg each

Sinus Pressure

Nasal & Sinus Congestion

72 Tablets

Actual Size



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ps) tever or other upper respiratory all ergies

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Drug Facts

NDC 81522-094-23

0926-617-008-1

Manufactured for FSA Store Inc. 240 W. 37th St. 6th Floor New York, NY 10018 Customer Care Help Line

*This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Sudated ƮCongestion.

QUESTIONS OF COMMENTS? 1-800-719-9 260

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polyethylene glycol, polyvinyl alcohol, sili con dioxide, talc, lecithin, ma gnesium stea rate, microcrystalline cellulose, phosphate, cam auba wax FD &C red n o. 40 aluminum lake, Inactive ingredients anhydrous dibasic calcium

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	Directions

Dung Facts (continued)

Imp ortant: Rea d all product in forma don before using. Ke ep this box for imp ortant information.





*Compare to the active ingredient of Sudafed PE® Congestion

Non-Drowsy · Maximum Strength

Nasal Decongestant

Phenylephrine HCl, 10 mg each

Sinus Pressure Nasal & Sinus Congestion

72 Tablets



Actual Size

CARING MILL SINUS PE

phenylephrine hydrochloride tablet, film coated

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:81522-094

Route of Administration ORAL

Active Ingredient/Active Moiety

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FD&C RED NO. 40 (UNII: WZB9127XOA)

Ingredient Name Basis of Strength Strength

PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)

PHENYLEPHRINE - PHENYLEPHRINE - HYDROCHLORIDE

Inactive Ingredients

Ingredient Name

CARNAUBA WAX (UNII: R12CBM0EIZ)

ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)

MAGNESIUM STEARATE (UNII: 70097M6I30)

MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)

POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3M)QOSDWIA)

POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)

TALC (UNII: 7SEV7J4R1U)

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

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:81522-094- 23	12 in 1 CARTON	01/12/2022		
1		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	01/12/2022	

Labeler - FSA Store Inc. (049283340)

Revised: 1/2022 FSA Store Inc.