

SUDOGEST PE- phenylephrine hydrochloride tablet, film coated

Major Pharmaceuticals

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.

Major Pharmaceuticals Sudogest™ 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?

1-800-616-2471

Principal Display Panel

Non-Drowsy

Compare to the active ingredient in Sudafed PE[®] Congestion

SUDOGEST[™] PE

Phenylephrine HCl, 10 mg each

NASAL DECONGESTANT

Does not contain Pseudoephedrine

1 Pill Per Dose

Nasal & Sinus Congestion

Sinus Pressure

Actual Size

36 TABLETS 10 mg EACH



SUDOGEST™ PE

NASAL DECONGESTANT

Non-Drowsy

NDC 0904-6753-73



Compare to the active ingredient
in Sudafed PE® Congestion*

SUDOGEST™ PE

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NASAL DECONGESTANT

Does not contain Pseudoephedrine

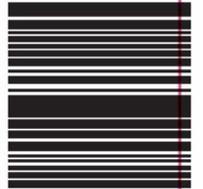
1 Pill Per Dose

- Nasal & Sinus Congestion
- Sinus Pressure



Actual Size

36 TABLETS
10 mg EACH



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

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Drug Facts (continued)

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- | | |
|--|---|
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Questions or comments? 1-800-616-2471

Gluten Free

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

Distributed by: MAJOR® PHARMACEUTICALS
17177 N Laurel Park Drive, Suite 233
Livonia, MI 48152
M-05 REV 04/18 Re-Order No. 700950

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SUDOGEST PE

phenylephrine hydrochloride tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0904-6753
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
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

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:0904-6753-49	18 in 1 CARTON	02/12/2019	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0904-6753-73	36 in 1 CARTON	02/12/2019	
2		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	02/12/2019	

Labeler - Major Pharmaceuticals (191427277)

Revised: 2/2019

Major Pharmaceuticals