

SINUS PE- phenylephrine hydrochloride tablet
L. Perrigo 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.

Perrigo 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	<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 Sudafed PE® Congestion active ingredient

MAXIMUM STRENGTH

sinus PE

Phenylephrine HCl Tablets – Nasal Decongestant

CONGESTION

Nasal & Sinus Congestion

Sinus Pressure

Non-Drowsy

Actual Size

24 TABLETS

10 mg EACH

MAXIMUM STRENGTH

sinus PE

Phenylephrine HCl Tablets - Nasal Decongestant

Compare to
Sudafed PE® Congestion
active ingredient*

NDC 0113-2004-62

MAXIMUM STRENGTH

sinus PE

Phenylephrine HCl Tablets - Nasal Decongestant

CONGESTION

- Nasal & Sinus Congestion
- Sinus Pressure

Non-Drowsy



Actual Size

24 TABLETS
10 mg EACH

: 0496 55 02

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

<p>Drug Facts</p> <p>Active ingredient (in each tablet) Purpose Phenylephrine HCl 10 mg.....Nasal decongestant</p> <p>Uses</p> <ul style="list-style-type: none"> ■ temporarily relieves sinus congestion and pressure ■ temporarily relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies <p>Warnings</p> <p>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.</p> <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> ■ heart disease ■ high blood pressure ■ thyroid disease ■ diabetes ■ trouble urinating due to an enlarged prostate gland <p>When using this product do not exceed recommended dosage</p> <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> ■ nervousness, dizziness, or sleeplessness occur ■ symptoms do not improve within 7 days or occur with a fever <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>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).</p>	<p>Drug Facts (continued)</p> <p>Directions</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">adults and children 12 years and over</td> <td style="width: 50%;"> <ul style="list-style-type: none"> ■ take 1 tablet every 4 hours ■ do not take more than 6 tablets in 24 hours </td> </tr> <tr> <td>children under 12 years</td> <td>ask a doctor</td> </tr> </table> <p>Other information</p> <ul style="list-style-type: none"> ■ store at 20-25°C (68-77°F) ■ do not use if blister unit is broken or torn <p>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</p> <p>Questions or comments? 1-800-719-9260</p> <p><small>*This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Sudafed PE® Congestion.</small></p> <p>Distributed By Perrigo® Allegan, MI 49010 perrigo.com</p>	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
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SINUS PE

phenylephrine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0113-2004
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)		
	MAGNESIUM STEARATE (UNII: 70097M6I30)		
	MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)		
	POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
	POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)		
	SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		

TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
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:0113-2004-62	24 in 1 CARTON	09/18/2015	
1		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	09/18/2015	

Labeler - L. Perrigo Company (006013346)

Revised: 12/2019

L. Perrigo Company