

CERTI-SINE- phenylephrine hydrochloride tablet
Certified Safety Manufacturing

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.

CERTI-SINE™

Drug Facts

Active Ingredients (each tablet)

Phenylephrine HCl 5 mg

Purpose

Nasal decongestant

Uses

- For the temporary relief of nasal congestion due to a cold, hay fever or other upper respiratory allergies associated with sinusitis.
- Temporarily relieves stuffy nose, sinus congestion and pressure.

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 health professional before taking this product.

Ask a doctor before use if you have

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- glaucoma
- trouble urinating due to an enlarged prostate gland.

Stop use and ask a doctor if

- new symptoms occur
- symptoms do not improve within 7 days
- redness or swelling are present
- you get nervous, dizzy or sleepless.

If pregnant or breast-feeding

- ask a health professional before use.

Keep out of the reach of children. In case of accidental overdose, contact a doctor or Poison Control Center (1-800-222-1222) immediately. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Do not exceed recommended dosage.

Directions

- **Adults and children 12 years of age and older** Take 2 tablets every 4 hours as needed. Do not take more than 12 tablets in 24 hours.
- **Children under 12 years of age** Do not use this adult strength product without first speaking to your doctor.

Other information

- read all product information before using
- store at room temperature 59-86°F (15-30°C)
- use by expiration date on package.

Inactive ingredients

- Colloidal silica, croscarmellose sodium, dicalcium phosphate, D & C Red #27 Lake, Magnesium Stearate, microcrystalline cellulose, pharmaceutical glaze, pregelatinized starch, stearic acid, talc.

Questions?

Call 1-800-854-7474

PRINCIPAL DISPLAY PANEL - 5 mg Tablet Pouch Box

**Tamper evident packaging:
Do not use if open or torn.**

This package for households without children

See New Warnings Information

Compare to Sudafed PE[®]

CERTI-SINE[™]

5 mg Phenylephrine HCl

- **Nasal Decongestant**

25 PACKAGES
2 TABLETS EACH

Certified
Safety
Mfg.



CERTI-SINE™

CERTI-SINE™

5 mg Phenylephrine HCl



• Descongestionante
Nasales

• Nasal
Decongestant

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Ask a doctor before use if you have • heart disease • high blood pressure • thyroid disease • diabetes • glaucoma • trouble urinating due to an enlarged prostate gland.

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Drug Facts (continued)

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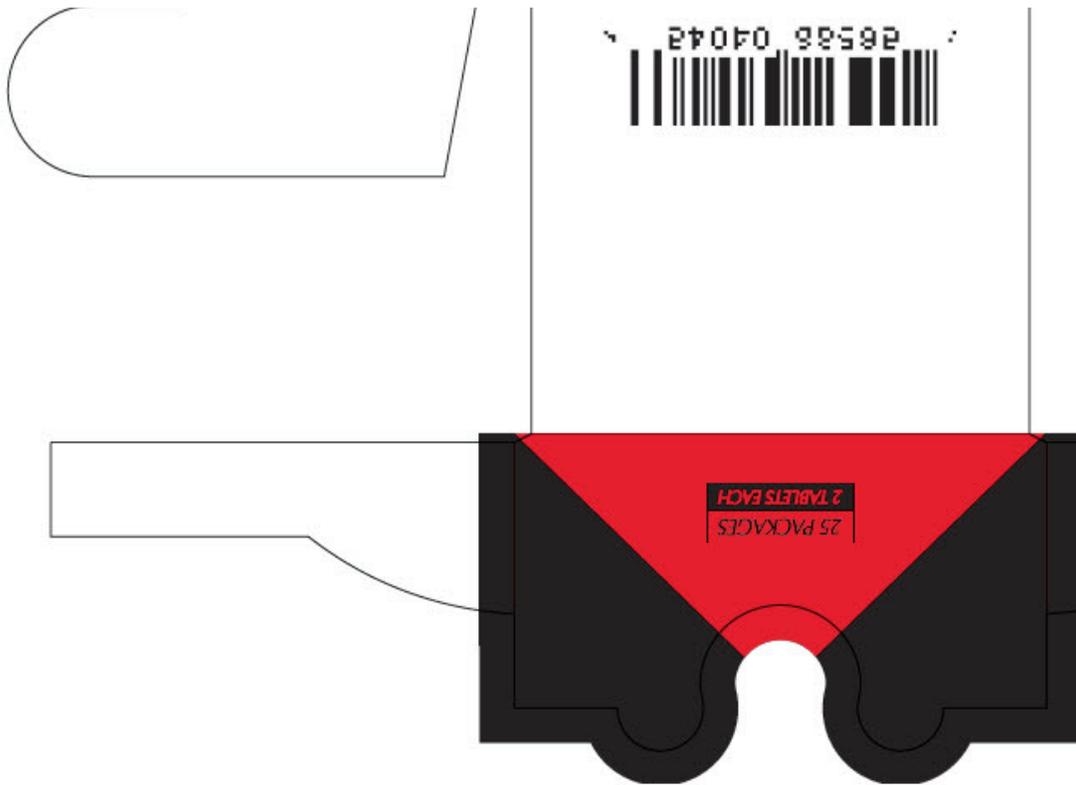
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Mfg. for: Certified Safety Mfg., Inc.
Kansas City, MO 64127

Reorder # 504-048





CERTI-SINE

phenylephrine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:48083-330
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SHELLAC (UNII: 46N107B71O)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	RED	Score	no score
Shape	ROUND	Size	7mm
Flavor		Imprint Code	271
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:48083-330-27	25 in 1 BOX	12/29/2017	
1		2 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:48083-330-30	50 in 1 BOX	12/29/2017	
2		2 in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:48083-330-33	125 in 1 BOX	12/29/2017	
3		2 in 1 POUCH; Type 0: Not a Combination Product		
4	NDC:48083-330-36	250 in 1 BOX	12/29/2017	
4		2 in 1 POUCH; Type 0: Not a Combination Product		
5	NDC:48083-330-39	500 in 1 BOX	12/29/2017	
5		2 in 1 POUCH; Type 0: Not a Combination Product		
6	NDC:48083-330-41	1000 in 1 BOX	12/29/2017	
6		2 in 1 POUCH; Type 0: Not a Combination Product		
7	NDC:48083-330-31	50 in 1 BOX	12/29/2017	
7		2 in 1 POUCH; 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	12/29/2017	

Labeler - Certified Safety Manufacturing (788460483)

Revised: 4/2018

Certified Safety Manufacturing