

HELP I HAVE A STUFFY NOSE - phenylephrine tablet

Help Remedies, 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.

Drugs Facts

**Active Ingredient.....Purpose
(in each tablet)**

Phenylephrine HCl (5 mg).....Nasal Decongestant

Uses

Temporarily relieves nasal congestion due to:

- the common cold
- hay fever or other upper respiratory allergies
- helps decongest sinus openings and passages; temporarily relieves 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 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.

Stop use and ask a doctor if

• you get nervous, dizzy, or sleepless • symptoms do not improve within 7 days or are accompanied by fever.

When using this product do not use more than directed

Keep out of reach of children.

In case of accidental overdose, contact a doctor or Poison Control Center immediately.

If pregnant or breast feeding, ask a health professional before use.

Directions

- adults and children 12 years of age and over: 2 tablets (10 mg) every 4 hours. • do not exceed 12 tablets (60 mg) in 24 hours
- children under 12 years of age: Consult a doctor

Other Information

• store at room temperature 15-30 degrees C (59-86 degrees F) in a dry place • do not use if blister package is torn. • keep container. They contain important information.

Inactive Ingredients

microcrystalline cellulose, magnesium stearate, silicon dioxide, dicalcium phosphate, starch, stearic acid, croscarmellose sodium

Distributed by Help Remedies,

57 W. 28th St. Fl. 4

New York, NY 10001

www.helpineedhelp.com

cover
typ 2.0"

Help I have a stuffy nose is for stuffy noses. If you are looking to treat a cough/ cold/ headache/ sore throat/ itchy eye/ aching toe, look somewhere else.



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Drug Facts

Active Ingredient (in each tablet)	Purpose
Phenylephrine HCl...Nasal decongestant 5 mg	

Uses • temporarily relieves nasal congestion due to: • the common cold • hay fever or other upper respiratory

DO NOT USE IF SEAL IS BROKEN OR TAMPERED WITH

PEEL HERE FOR MORE DRUG FACTS →

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typ 2.0"

Drug Facts (continued)

allergies

- helps decongest sinus openings and passages; temporarily relieves sinus congestion and pressure

Warnings

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typ 1.75"

Drug Facts (continued)

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 use more than directed

Stop use and ask a doctor if

- you get nervous, dizzy, or sleepless • symptoms do not improve within 7 days or are accompanied by fever

→

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typ 1.75"

Drug Facts (continued)

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 immediately.

Directions

- adults and children 12 years of age and over: 2 tablets (10 mg) every 4 hours • do not exceed 12 tablets (60 mg) in 24 hours
- children under 12 years: consult a doctor

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Base Web
2.25" X 2.25" label size

Drug Facts (continued)

Other Information

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Inactive Ingredients

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HELP I HAVE A STUFFY NOSE

phenylephrine tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49260-716
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

UNII:1WS297W6MV)	HYDROCHLORIDE	5 mg
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Inactive Ingredients

Ingredient Name	Strength
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	white (white)	Score	no score
Shape	ROUND (round tablet)	Size	7mm
Flavor		Imprint Code	FR4
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49260-716-50	50 in 1 BOTTLE		
2	NDC:49260-716-16	16 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	05/01/2012	

Labeler - Help Remedies, Inc. (050359682)

Registrant - Help Remedies, Inc. (050359682)