NASAL DECONGESTANT- phenylephrine hydrochloride tablet, coated Marc Glassman, 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.

1131 - MAR - 2018-1211

Drug Facts

Active ingredient (in each tablet)

Phenylephrine HCl 10 mg

Purpose

Nasal decongestant

Uses

- temporarily relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies, and nasal congestion associated with sinusitis
- 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

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

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.

Directions

 adults and children 12 years of age and over: take 1 tablet every 4 hours; do not take more than 6 tablets in 24 hours • children under 12 years of age: ask a doctor

Other information

- store at 15°-25°C (59°-77°F) in a dry place
- retain carton for complete product information

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, D&C red #27, FD&C red #40, FD&C yellow #6, hypromellose, lactose anhydrous, magnesium stearate, polyethylene glycol, stearic acid, titanium dioxide

PRINCIPAL DISPLAY PANEL

†Compare to the active ingredient in Sudafed PE® Congestion

Marc's®

Non-Drowsy

Nasal Decongestant PE

Maximum Strength

Phenylephrine HCl

For Relief Of:

• Sinus Pressure & Congestion

18 Tablets

10 mg Each

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Nasal decongestant Purpose

Phenylephrine HCI 10 mg. Active ingredient (in each tablet)

Drug Facts

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Marc's.

maximum strength, non-drowsy

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Other information

Orug Facts (continued)

Directions

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Nasal Decongestant PE

ingredient in Sudafed PE®

10 mg each

Marc's.

non-drowsy

Nasal Decongestant PE

MAXIMUM STRENGTH

Phenylephrine HCI

For Relief of:

Sinus Pressure & Congestion

18 Tablets

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

Distributed by: Marc Glassman, Inc. West 130th Street Cleveland, OH 44130

USE IF BLISTER UNITS TORN OR BROKEN NOT L

Marc's.

maximum strength, non-drowsy

Nasal Decongestant PE

18 Tablets 10 mg each



phenylephrine hydrochloride tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68998-131
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
PHENYLEPHRINE HYDRO CHLO RIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg	

Inactive Ingredients		
Ingredient Name	Strength	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)		
D&C RED NO. 27 (UNII: 2LRS 185U6K)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)		
HYPROMELLOSES (UNII: 3NXW29 V3WO)		
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)		

Product Characteristics			
Color	red	Score	no score
Shape	ROUND	Size	7mm
Flavor		Imprint Code	A;131
Contains			

l	Packaging				
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
	1 NDC:68998-131-02	2 in 1 CARTON	03/01/2008		
	1	9 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	03/01/2008	

Revised: 12/2018 Marc Glassman, Inc.