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

NASAL DECONGESTANT

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 HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg

Inactive Ingredients	
Ingredient Name	**Strength**
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

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

Packaging				
#	**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	

Labeler - Marc Glassman, Inc. (094487477)