SINUS CONGESTION PE MAXIMUM STRENGTH- 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-2022-1005

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 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 between 20-25°C (68-77°F) in a dry place
- retain carton for complete product information and warnings

Inactive ingredients

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

PRINCIPAL DISPLAY PANEL

Marc's®

NDC 68998-231-02

†Compare to the active ingredient in Sudafed PE® Sinus Congestion

Maximum Strength • Non-Drowsy

Sinus Congestion PE

Phenylephrine HCl

NASAL DECONGESTANT

For Relief of:

• Sinus Pressure

• Sinus Congestion

Actual Size

18 TABLETS - 10 MG EACH

Marc's

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DO NOT USE IF BLISTER UNITS ARE TORN OR BROKEN

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

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

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SINUS CONGESTION PE MAXIMUM STRENGTH

phenylephrine hydrochloride tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68998-231
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)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
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: 3WQ0SDW1A)	
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:68998-231-02	1 in 1 PACKAGE	10/05/2022	
1		18 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End

Category	Citation	Date	Date
OTC monograph final	part341	10/05/2022	

Labeler - MARC GLASSMAN, INC. (094487477)

Revised: 10/2022 MARC GLASSMAN, INC.