PHENYLEPHRINE HYDROCHLORIDE- phenylephrine hydrochloride tablet, coated
AAA Pharmaceutical, 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.

RES - 1131 - 2019-1014

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 - 36 Tablet Blister Pack Carton

RESTORE U

NDC 57344-131-03

†COMPARE TO THE ACTIVE INGREDIENT IN SUDAFED PE ® NASAL DECONGESTANT

MAXIMUM STRENGTH

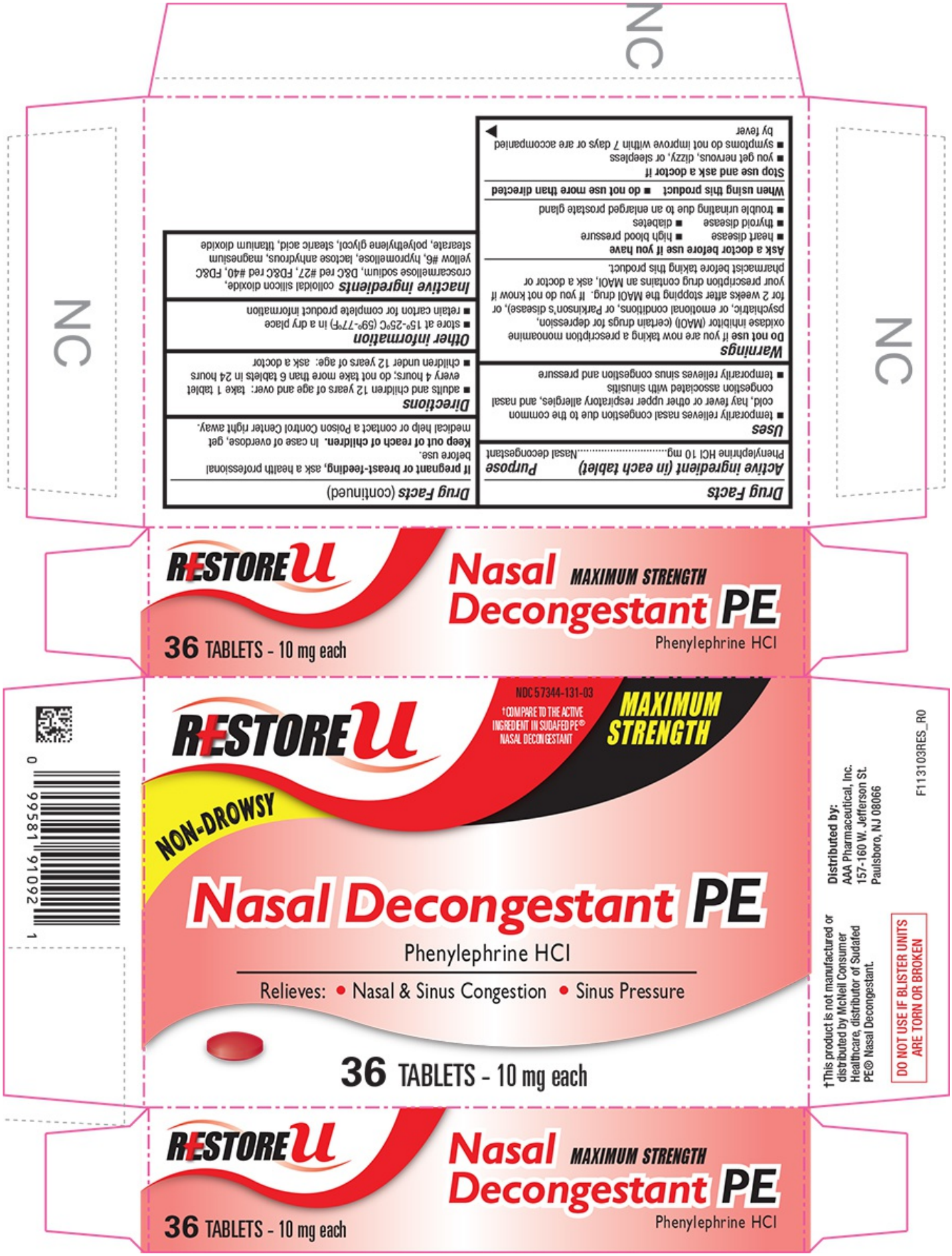
NON-DROWSY

Nasal Decongestant PE

Phenylephrine HCl

Relieves: • Nasal & Sinus Congestion • Sinus Pressure

36 TABLETS - 10 mg each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NC
NC
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RESTORE U
36 TABLETS - 10 mg each
Nasal MAXIMUM STRENGTH Decongestant PE
Phenylephrine HCl
NDC 57344-131-03
†COMPARE TO THE ACTIVE INGREDIENT IN SUDAFED PE® NASAL DECONGESTANT
MAXIMUM STRENGTH
NON-DROWSY
Nasal Decongestant PE
Phenylephrine HCl
Relieves: • Nasal & Sinus Congestion • Sinus Pressure
36 TABLETS - 10 mg each
†This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Sudafed PE® Nasal Decongestant.
Distributed by:
AAA Pharmaceutical, Inc.
157-160 W. Jefferson St.
Paulsboro, NJ 08066
DO NOT USE IF BLISTER UNITS ARE TORN OR BROKEN
F113103RES_R0
0 99581 91092 1
RESTORE U
36 TABLETS - 10 mg each
Nasal MAXIMUM STRENGTH Decongestant PE
Phenylephrine HCl

PHENYLEPHRINE HYDROCHLORIDE

phenylephrine hydrochloride tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:57344-131
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)	
HYPROMELLOSE, UNSPECIFIED (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:57344-131-03	2 in 1 CARTON	04/13/2012	
1		18 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	04/13/2012	

Labeler - AAA Pharmaceutical, Inc. (181192162)

Revised: 10/2019 AAA Pharmaceutical, Inc.