

**ASSURED MAXIMUM STRENGTH NASAL DECONGESTANT- phenylephrine hcl tablet**  
**Spirit Pharmaceuticals LLC**

*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.*

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**Assured Maximum Strength Nasal Decongestant 24ct**

**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 dose**

**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)

**Drug Facts** (continued)

## Directions

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adults and children 12 years  
and over

■ take 1 tablet every 4 hours  
■ do not take more than 6 tablets in  
24 hours

children under 12 years

ask a doctor

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## Other information

store between 20° to 25°C (68° to 77°F)

## Inactive ingredients

croscarmellose sodium, FD&C red #40 aluminum lake, FD&C yellow #6 aluminum lake, hypromellose, lactose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, silicon dioxide, titanium dioxide

**Questions or comments? 1-888-333-9792**

## PRINCIPAL DISPLAY PANEL

ASSURED

COMPARE TO ACTIVE INGREDIENT IN  
SUDAFED® PE CONGESTION®†

MAXIMUM STRENGTH

Nasal Decongestant

· Phenylephrine HCl 10 mg - Nasal Decongestant

Relieves Nasal & Sinus Congestion,  
Reduces Sinus Pressure, Non-Drowsy

Actual Size

PSEUDOEPHEDRINE FREE

24tablets

†This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Sudafed PE® Congestion



# ASSURED MAXIMUM STRENGTH NASAL DECONGESTANT

phenylephrine hcl tablet

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68210-0118
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength		
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg		
<b>Inactive Ingredients</b>				
Ingredient Name	Strength			
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)				
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)				
LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
<b>Product Characteristics</b>				
Color	red	Score	no score	
Shape	CAPSULE	Size	8mm	
Flavor		Imprint Code	T234	
Contains				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-0118-3	1 in 1 CARTON	02/26/2019	
1		24 in 1 BLISTER PACK; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part341	02/26/2019		

**Labeler** - Spirit Pharmaceuticals LLC (179621011)

### Establishment

Name	Address	ID/FEI	Business Operations
Time Cap Laboratories, Inc		037052099	manufacture(68210-0118)