

**NASAL AND SINUS DECONGESTANT- nasal and sinus decongestant tablet  
Redicare 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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**Decongestant**

**Active Ingredient (in each tablet).....**

**Purpose**

Phenylephrine HCl 5  
mg.....Decongestant

**Uses:**

Temporarily: ■ relieves nasal congestion associated with sinusitis ■ relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies ■ relieves sinus congestion and pressure, helps decongest sinus opening and passages ■ restores free breathing

**Warnings:**

**Do not use:**

■ more than recommended dose ■ 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 MAOI drug. If you do not know if your prescription drug contains a MAOI, consult a doctor or pharmacist before taking this product.

**Stop use and ask a doctor if**

■ symptoms do not improve ■ new symptoms occur ■ redness or swelling is present ■ nervousness, dizziness or sleeplessness occur ■ symptoms do not improve within 7 days or are accompanied by fever

**Ask a doctor before use if you have:**

■ heart disease ■ high blood pressure ■ thyroid disease ■ diabetes ■ difficulty in urination due to enlargement of the prostate gland

**If pregnant or breast-feeding a baby,**

ask a health professional before use.

## KEEP OUT OF REACH OF CHILDREN.

In a case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

### Directions:

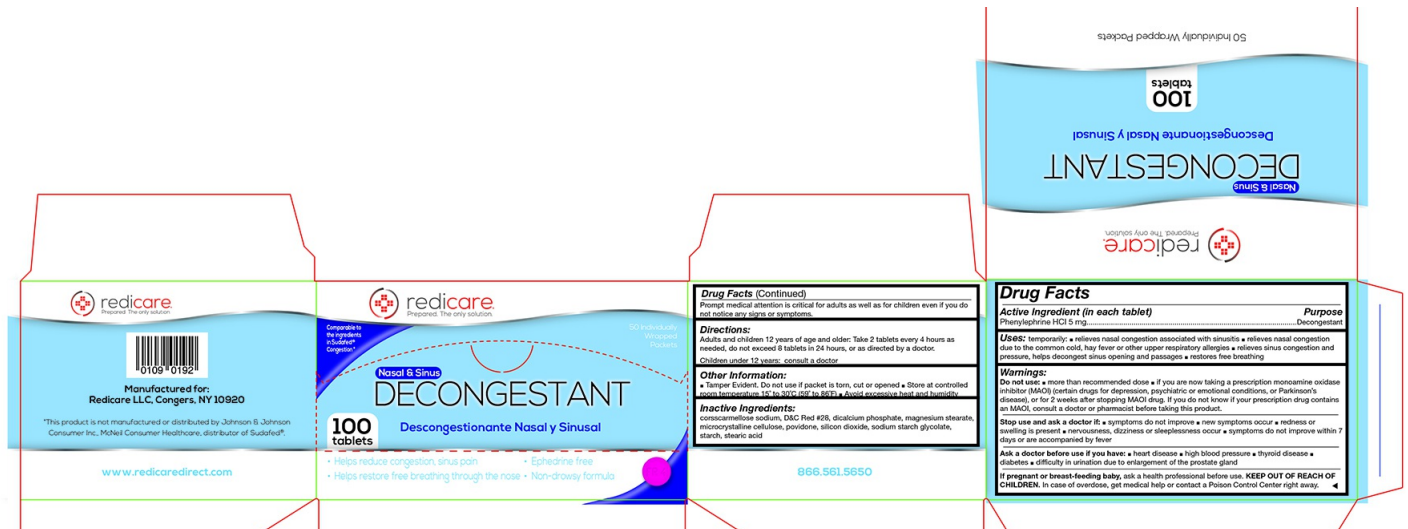
Adults and children 12 years of age and older: Take 2 tablets every 4 hours as needed, do not exceed 8 tablets in 24 hours, or as directed by a doctor.  
Children under 12 years: consult a doctor

### Other Information:

■ Tamper Evident. Do not use if packet is torn, cut or opened ■ Store at controlled room temperature 15° to 30°C (59° to 86°F) ■ Avoid excessive heat and humidity

### Inactive Ingredients:

cornstarch, croscarmellose sodium, D&C Red #28, dicalcium phosphate, magnesium stearate, microcrystalline cellulose, povidone, silicon dioxide, sodium starch glycolate, starch, stearic acid



## NASAL AND SINUS DECONGESTANT

nasal and sinus decongestant tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71105-333
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	<b>PHENYLEPHRINE HYDROCHLORIDE</b>	5 mg
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### Inactive Ingredients

Ingredient Name	Strength
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>D&amp;C RED NO. 28</b> (UNII: 767IP0Y5NH)	
<b>CALCIUM PHOSPHATE, DIBASIC, DIHYDRATE</b> (UNII: O7TSZ97GEP)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>SODIUM STARCH GLYCOLATE TYPE A CORN</b> (UNII: AG9B65PV6B)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	

### Product Characteristics

<b>Color</b>	pink	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	6mm
<b>Flavor</b>		<b>Imprint Code</b>	FR4
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71105-333-68	100 in 1 CARTON; Type 0: Not a Combination Product	10/01/2017	



### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	02/01/2017	

**Labeler** - Redicare LLC (800149346)