

**SEVERE SINUS CONGESTION RELIEF- acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride capsule, liquid filled**  
**Pharmacy Value Alliance, 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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**Severe Congestion Relief**

**Active ingredients (in each softgel)**

**Acetaminophen 325 mg**

Dextromethorphan HBr 10 mg

Guaifenesin 200 mg

Phenylephrine HCl 5 mg

**Purpose**

**Pain reliever**

Cough suppressant

Expectorant

Nasal decongestant

**Uses**

- temporarily relieves:
  - nasal congestion
  - headache
  - minor aches and pains
  - sinus congestion and pressure
  - cough
- temporarily promotes nasal and/or sinus drainage
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive

**Warnings**

**Liver warning**

This product contains acetaminophen. Severe liver damage may occur if you take

- more than 12 liquid gels in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks daily while using this product

**Allergy alert:** Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

**Do not use**

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- 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**

- liver disease
- heart disease
- diabetes
- high blood pressure
- thyroid disease
- trouble urinating due to enlarged prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- cough that occurs with too much phlegm (mucus)

**Ask a doctor or pharmacist before use if you are**

taking the blood thinning drug warfarin

**When using this product, do not use more than directed****Stop use and ask a doctor if**

- nervousness, dizziness or sleeplessness occur
- pain, nasal congestion, or cough gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back, or occurs with rash or headache that lasts.

These could be signs of a serious condition.

**If pregnant or breast-feeding**, ask a health professional before use.

**Keep out of reach of children.**

**Overdose warning:**

Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

**Directions**

- **do not take more than directed (see Overdose warning)**
- do not take more than 12 liquid gels in any 24-hour period
- adults and children 12 years of age and older: take 2 liquid gels every 4 hours

- children under 12 years of age: do not use

**Other information**

- store between 20-25°C (68-77°F)
- avoid excessive heat

**Inactive ingredients**

FD&C yellow #6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution, and white edible ink

**Questions or Comments?**

Call toll free: **1-800-719-9260**

**PRINCIPAL DISPLAY PANEL - Carton Label**

Severe Congestion Relief 16 SOFTGELS

\*Compare to the active ingredients in Mucinex<sup>®</sup> Sinus-Max<sup>®</sup> Severe Congestion Relief



# Severe Congestion Relief

THIS PRODUCT IS PACKAGED IN A CHILD RESISTANT AND TAMPER EVIDENT PACKAGE. USE ONLY IF BLISTERS ARE INTACT.

NDC 68016-148-16



\*\*\*COMPARE TO THE ACTIVE INGREDIENTS IN MUCINEX®  
SINUS-MAX® SEVERE CONGESTION RELIEF



**Severe  
Congestion Relief**

# Severe Congestion Relief

## MULTI-SYMPTOM RELIEF

**Acetaminophen** – Pain Reliever/Fever Reducer  
**Dextromethorphan HBr** – Cough Suppressant  
**Guaifenesin** – Expectorant  
**Phenylephrine HCl** – Nasal Decongestant

- Relieves Sinus Congestion
- Thins & Loosens Mucus
- Relieves Headache
- Controls Cough



Actual Size

**16** Softgels



LOT NO:

EXP DATE:



8 40986 03460 2

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

<b>Drug Facts</b>		<b>Drug Facts (continued)</b>	
<b>Active ingredients (in each softgel)</b>		<b>Purposes</b>	
Acetaminophen 325 mg.....Pain reliever		■ trouble urinating due to an enlarged prostate gland	
Dextromethorphan HBr 10 mg.....Cough suppressant		■ persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema	
Guaifenesin 200 mg.....Expectorant		■ cough that occurs with too much phlegm (mucus)	
Phenylephrine HCl 5 mg.....Nasal decongestant		Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin	
<b>Uses</b>		When using this product do not use more than directed	
■ temporarily relieves:		Stop use and ask a doctor if	
■ nasal congestion		■ nervousness, dizziness, or sleeplessness occur	
■ headache		■ pain, nasal congestion, or cough gets worse or lasts more than 7 days	
■ minor aches and pains		■ fever gets worse or lasts more than 3 days	
■ sinus congestion and pressure		■ redness or swelling is present	
■ cough		■ new symptoms occur	
■ temporarily promotes nasal and/or sinus drainage		■ cough comes back, or occurs with rash or headache that lasts. These could be signs of a serious condition.	
■ helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive		If pregnant or breast-feeding, ask a health professional before use.	
<b>Warnings</b>		Keep out of reach of children.	
Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take:		Overdose warning: Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.	
■ more than 12 softgels in 24 hours, which is the maximum daily amount		<b>Directions</b>	
■ with other drugs containing acetaminophen		■ do not take more than directed (see Overdose warning)	
■ 3 or more alcoholic drinks daily while using this product		■ do not take more than 12 softgels in any 24-hour period	
Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:		■ adults and children 12 years of age and older: take 2 softgels every 4 hours	
■ skin reddening ■ blisters ■ rash		■ children under 12 years of age: do not use	
If a skin reaction occurs, stop use and seek medical help right away.		<b>Other information</b>	
<b>Do not use</b>		■ store between 15-30°C (59-86°F)	
■ with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.		■ avoid excessive heat	
■ 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.		<b>Inactive ingredients</b>	
<b>Ask a doctor before use if you have</b>		FD&C yellow #6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution, and white edible ink	
■ liver disease		<b>Questions or comments?</b>	
■ heart disease		Call toll free: 1-800-719-9260	
■ diabetes		**This product is not manufactured or distributed by Reckitt Benckiser, owner of the registered trademarks Mucinex® Sinus-Max® Severe Congestion Relief.	
■ high blood pressure			
■ thyroid disease			

\*Per 4-hour dose.  
Do not take more than a total of 12 softgels in a 24-hour period.  
Take only as directed.



**PARENTS:**  
Learn about teen medicine abuse  
[www.StopMedicineAbuse.org](http://www.StopMedicineAbuse.org)



If for any reason you are not satisfied with this product, please return it to the store where purchased for a full refund.

Distributed By:  
Pharmacy Value Alliance, LLC  
407 East Lancaster Avenue,  
Wayne, PA 19087  
MADE IN CHINA  
PN XXXXXX

PRE02-00

## SEVERE SINUS CONGESTION RELIEF

acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride capsule, liquid filled

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68016-148
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg

<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SORBITAN</b> (UNII: 6O92ICV9RU)	
<b>WATER</b> (UNII: 059QF0K00R)	

### Product Characteristics

<b>Color</b>	orange (Clear)	<b>Score</b>	no score
<b>Shape</b>	capsule (Oblong)	<b>Size</b>	25mm
<b>Flavor</b>		<b>Imprint Code</b>	PC26
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-148-16	2 in 1 CARTON	08/23/2017	
1		8 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	08/23/2017	

**Labeler** - Pharmacy Value Alliance, LLC (101668460)

### Establishment

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceuticals (Wuhan) Co., Ltd		421293287	manufacture(68016-148) , analysis(68016-148)