

**MUCUS RELIEF SINUS SEVERE CONGESTION RELIEF- acetaminophen, guaifenesin, and phenylephrine hydrochloride tablet, coated**  
**CHAIN DRUG CONSORTIUM**

*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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**1167-PRV-2020-0901**

***Drug Facts***

<b><i>Active ingredients (in each caplet)</i></b>	<b><i>Purpose</i></b>
Acetaminophen 325 mg	Pain reliever
Guaifenesin 200 mg	Expectorant
Phenylephrine HCl 5 mg	Nasal decongestant

**Uses**

- temporarily relieves:
  - nasal congestion
  - headache
  - minor aches and pains
  - sinus congestion and pressure
- 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 caplets 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 an 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 persistent headache

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 (1-800-222-1222). 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 caplets in any 24-hour period
- adults and children 12 years and older: take 2 caplets every 4 hours
- children under 12 years of age: do not use

**Other information**

- store between 20-25°C (68-77°F) in a dry place
- retain outer package for complete product information

**Inactive ingredients**

colloidal silicon dioxide, croscarmellose sodium, crospovidone, FD&C red #40 aluminum lake, FD&C yellow #6 aluminum lake, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, stearic acid, talc, titanium dioxide

**Questions or comments?**

1-844-705-4384

## **PRINCIPAL DISPLAY PANEL**

Premier Value®

COMPARE TO THE ACTIVE INGREDIENTS IN MUCINEX® SINUS-MAX™ SEVERE  
CONGESTION RELIEF†

MAXIMUM STRENGTH\*

Mucus Relief Sinus

SEVERE CONGESTION RELIEF

Acetaminophen, Guaifenesin, Phenylephrine HCl

Pain Reliever, Expectorant, Nasal Decongestant

- Clears Sinus Congestion
- Relieves Headache
- Thins & Loosens Mucus

ACTUAL SIZE

20 CAPLETS

For Ages 12+



acetaminophen, guaifenesin, and phenylephrine hydrochloride tablet, coated				
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68016-549	
Route of Administration	ORAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)		ACETAMINOPHEN	325 mg	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)		GUAIFENESIN	200 mg	
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)		PHENYLEPHRINE HYDROCHLORIDE	5 mg	
Inactive Ingredients				
Ingredient Name			Strength	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)				
CROSPVIDONE (UNII: 2S7830E561)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
ALUMINUM OXIDE (UNII: LM26O6933)				
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
MALTODEXTRIN (UNII: 7CVR7L4A2D)				
CELLULOSE, MICROCRYSTALLINE (UNII: OPIR32D61U)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
POLYVINYL ALCOHOL (UNII: 532B59J990)				
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)				
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
TALC (UNII: 7SEV7J4R1U)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
Product Characteristics				
Color	orange	Score	no score	
Shape	OVAL	Size	19mm	
Flavor		Imprint Code	AAA;1166	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-549-20	2 in 1 CARTON	09/01/2014	
1		10 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	09/01/2014	

**Labeler** - CHAIN DRUG CONSORTIUM (101668460)

Revised: 9/2020

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