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.

1167-PRV-2020-0901

Drug Facts

Active ingredients (in each caplet)	Purpose
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?

PRINCIPAL DISPLAY PANEL

Premier Value®

COMPARE TO THE ACTIVE INGREDIENTS IN MUCINEX® SINUS-MAXTM 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+

ARE TORN OR BROKEN DO NOT USE IF BLISTER UNITS If for any reason you are not satisfied with this product, please return it to the store where purchased for a full refund.

*Per 4-hour dose, dose every 4 hours

Questions or comments? **Drug Facts** (continued)

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distributed by Reckitt Benckiser, distributor of Mucinex $^{\otimes}$ Sinus-Max $^{\text{TM}}$ Severe Congestion Relief. This product is not manufactured or

Wayne, PA 19087 Pharmacy Value Alliance, LLC 407 East Lancaster Avenue Distributed By:

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SEVERE CONGESTION RELIEF

Drug Facts (continued)

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Nasal decongestant

Phenylephrine HCl 5 mg.

Suaifenesin 200 mg.

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■ minor aches and pains Uses ■ temporarily relieves: ■ headache

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the MA01 drug. If you do not know if your prescription drug contains an MA01, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

diabetes heart disease

 thyroid disease cough that occurs with too much phlegm (mucus) trouble urinating due to an enlarged prostate high blood pressure

polyvinyl alcohol, povidone, pregelatinized starch stearic acid, talc, titanium dioxide

microcrystalline cellulose, polyethylene glycol,

dioxide, croscarmellose sodium, crospovídone, FD&C red #40 aluminum kake, FD&C yellow #6 aluminum lake, magnesium stearate, mattodextrin,



F116702PRV_R1

Premier Value

Active ingredients (in each caplet)

Drug Facts

MAXIMUM STRENGTH*

Mucus Relief Sinus

SEVERE CONGESTION RELIE

Premier Value°

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

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

For Ages 12+



20 CAPLETS

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	
ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D)	ACETAMINOPHEN	325 mg	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg	
PHENYLEPHRINE HYDRO CHLO RIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg	

Inactive Ingredients	
Ingredient Name	Strength
SILICON DIO XIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)	
CROSPO VIDO NE (UNII: 2S7830E561)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTO DEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
PO VIDO NE, UNSPECIFIED (UNII: FZ989GH94E)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	

Product Characteristics				
Color	orange	Score	no score	
Shape	OVAL	Size	19 mm	
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 CHAIN DRUG CONSORTIUM