# MUCUS RELIEF SINUS SEVERE CONGESTION AND PAIN- acetaminophen, guaifenesin, and phenylephrine hydrochloride tablet, coated AMERISOURCE BERGEN

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#### 1167-GNP-2022-1123

# **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, corn starch, 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

#### PRINCIPAL DISPLAY PANEL

GOOD NEIGHBOR PHARMACY®

Compare to Mucinex® Sinus-Max® Severe Congestion & Pain active ingredients†

NDC 46122-712-60

Maximum Strength

For Ages 12+

Mucus Relief Sinus Severe Congestion & Pain

Acetaminophen, guaifenesin, phenylephrine hcl

pain reliever, experctorant, nasal decongestant

- Clears Sinus Congestion Relieves Headache
- Thins & Loosens Mucus

20 CAPLETS

actual size

# **MUCUS RELIEF SINUS SEVERE CONGESTION AND PAIN**

acetaminophen, guaifenesin, and phenylephrine hydrochloride tablet, coated

#### **Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:46122-712
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Route of Administration ORAL

# Active Ingredient/Active Moiety Ingredient Name Basis of Strength ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D) GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ) PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV) PHENYLEPHRINE 5 mg

Inactive Ingredients		
Ingredient Name	Strength	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
STARCH, CORN (UNII: O8232NY3SJ)		
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)		
CROSPOVIDONE (UNII: 2S7830E561)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
ALUMINUM OXIDE (UNII: LMI2606933)		
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
MALTODEXTRIN (UNII: 7CVR7L4A2D)		
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)		
POVIDONE (UNII: FZ989GH94E)		
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	
<b>1</b> NDC:46122-712-60	2 in 1 CARTON	05/01/2022		
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 Drug	M012	05/01/2022	

# Labeler - AMERISOURCE BERGEN (007914906)

Revised: 2/2024 AMERISOURCE BERGEN