MUCUS RELIEF SINUS SEVERE CONGESTION RELIEF- acetaminophen, guaifenesin, and phenylephrine hydrochloride tablet, coated Chain Drug Marketing Association

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.

QCH - 1167 - 2019-1007

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

PRINCIPAL DISPLAY PANEL

Quality Choice®

NDC 63868-722-20

†Compare to Active Ingredients in Mucinex ® Sinus-Max[™] Severe Congestion Relief

Maximum Strength*

Mucus Relief Sinus

Severe Congestion Relief

Pain Reliever, Expectorant, Nasal Decongestant

Acetaminophen, Guaifenesin, Phenylephrine HCl

For Relief of:

Sinus Congestion

Headache

Thins & Loosens Mucus

For Ages 12+

20 Caplets



MUCUS RELIEF SINUS SEVERE CONGESTION RELIEF

acetaminophen, guaifenesin, and phenylephrine hydrochloride tablet, coated

Product Informatio	n						
Product Type	HUMAN OTC	DRUG	Item Code	Code (Source) NDC:63868		68-722	
Route of Administratio	n ORAL						
Active Ingredient/Ac	ctive Moiety						
	Ingredient Name Basis of St			rength	Strength		
	IEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII: 36209ITL9D) ACETAMINOPHEN			J	325 mg		
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)			GUAIFENESIN		200 mg		
			HYDROCHLORIDE	IENYLEPHRINE /DROCHLORIDE 5 mg			
Inactive Ingredients	5						
	Ingredie	ent Name			S	trength	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)							
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)							
CROSPOVIDONE, UNSPECIFIED (UNII: 2S7830E561)							
FD&C RED NO. 40 (UNII: W							
FD&C YELLOW NO. 6 (UNI							
	· ·						
MALTODEXTRIN (UNII: 7CVR7L4A2D)							
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)							
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)							
POVIDONE, UNSPECIFIED (UNII: FZ 989GH94E)							
STARCH, CORN (UNII: 0823							
STEARIC ACID (UNII: 4ELV7	-						
TALC (UNII: 7SEV7J4R1U)							
TITANIUM DIOXIDE (UNII: 1	L5FIX9V2JP)						
Product Characteris	stics						
Color	orange	Score		n	o score		
Shape	OVAL	Size 19mm		9mm			
Flavor		Imprint C	ode	A	AA;1166		
Contains							
Packaging							
# Item Code	Package Des	cription	Ma	rketing Start Date		ting End ate	
1 NDC:63868- 722-20 2 in 1 C	ARTON		06/1	0/2015			
	BLISTER PACK; Type	0: Not a Comb	oination				

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph final	part341	06/10/2015				

Labeler - Chain Drug Marketing Association (011920774)

Revised: 12/2022

Chain Drug Marketing Association