MUCUS RELIEF SINUS SEVERE CONGESTION RELIEF- acetaminophen, guaifenes in, 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-MaxTM 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

henylephrine HCl 5 mg. Active ingredients in each caplet) uaifenesin 200 mg.

Ises temporarily relieves:

minor aches and pains

Drug Facts (continued)

*Compare to

When using this product do not use more than are taking the blood thinning drug warfarin Ask a doctor or pharmacist before use if you

Active Ingredients In MUCINEX® Sinus-Max™

NDC 63868-722-20

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Maximum Strength*

Mucus Relief Sinus Severe Congestion Relief

Pain Reliever, Expectorant, Nasal Decongestant







Ask a doctor before use if you have diabetes

FD&C red #40 aluminum lake, FD&C yellow #6

microcrystalline cellulose, polyethylene glycol

vinyl alcohol, povidone, pregelatinized starch

or pharmacist before taking this product. the MA0I drug. If you do not know if your

drug contains an MAOI, ask a doctor

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colloidal silicon

Other information

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oxidase inhibitor (MAOI) (certain drugs for

depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping

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

24-hour period
adults and children 12 years and older: take 2

do not take more than 12 caplets in any

directed (see Overdose warning)

Directions

do not take more than

children under 12 years of age: do not use

caplets every 4 hours

not use

Maximum Strength*

Mucus Relief Sinus Severe Congestion Relief

Pain Reliever, Expectorant, Nasal Decongestant

Acetaminophen, Guaifenesin, Phenylephrine HCI

For Relief of: Sinus Congestion Headache

Thins & Loosens Mucus

For Ages 12+ Actual Size



F116702QCH R0

20 Caplets



†This product is not manufactured or distributed by Reckitt Benckiser, distributor of Mucinex® Sinus-Max™ Severe Congestion Relief.

DO NOT USE IF BLISTER UNITS ARE TORN OR BROKEN

*Per 4-hour dose, dose every 4 hours

Maximum Strength*
Mucus Relief Sinus
Severe Congestion Relief

acetaminophen, guaifenesin, and phenylephrine hydrochloride tablet, coated

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-722	
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: ETJ7Z6 XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28 OL 1 HH 48)	
CROSPOVIDONE, UNSPECIFIED (UNII: 2S7830E561)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
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, UNSPECIFIED (UNII: 532B59J990)	
PO VIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STARCH, 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:63868-722- 20	2 in 1 CARTON	06/10/2015		
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	06/10/2015	

Labeler - Chain Drug Marketing Association (011920774)

Revised: 10/2019 Chain Drug Marketing Association