

**MUCUS RELIEF SEVERE CONGESTION AND SINUS- acetaminophen,
dextromethorphan hbr, guaifenesin, phenylephrine hcl capsule
QUALITY CHOICE (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.

Drug Facts

Active ingredients (in each softgels)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Guaifenesin 200 mg

Phenylephrine HCL 5 mg

Purposes

Pain reliever

Cough suppressant

Expectorant

Nasal decongestant

Uses

- temporarily relieves
 - cough due to inhaled irritants
 - nasal congestion
 - headache
 - sinus congestion and pressure
 - minor ache and pain
- temporarily promoted 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 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day 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
- diabetes
- high blood pressure
- heart disease
- 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

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 fever, rash, or headache that lasts. 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 (1-800-222-1222) right away. 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 softgels in any 24-hour period
- adults and children 12 years and older: take 2 softgels every 4 hours
- children under 12 years of age: do not use

Other information

- store between 20-25°C (68-77°F)
- avoid excessive heat
- swallow whole; do not crush, chew, or dissolve

Inactive ingredients

FD&C red 40, FD&C yellow #6, gelatin, glycerin, mannitol, polyethylene glycol, povidone, propylene glycol, purified water, sorbitan, sorbitol, titanium dioxide

Questions or comments?

Call **1-800-935-2362** Monday-Friday 9AM-5PM EST

Principal Display Panel

†Compare to the Active Ingredients in Mucinex® Maximum Strength Sinus-Max® Severe Congestion Relief

Maximum Strength

Mucus Relief

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Guaifenesin 200 mg

Phenylephrine HCL 5 mg

Pain Reliever | Cough Suppressant

Expectorant | Nasal Decongestant

Relieves Sinus Congestion

Thins & Loosens Mucus
Relieves Headache
Controls Cough
For Ages 12 Years & Older
Alcohol Free
Softgels**

(**Liquid-Filled Capsules)

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

TAMPER EVIDENT: DO NOT USE IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Distributed by: C.D.M.A., Inc. ©

43157 W 9 Mile Rd

Novi, MI 48375

www.qualitychoice.com

Package Label

Drug Facts	
Active ingredients (in each softgel)	Purposes
Acetaminophen 325 mg.....	Pain reliever
Dextromethorphan HBr 10 mg.....	Cough suppressant
Guaifenesin 200 mg.....	Expectorant
Phenylephrine HCl 5 mg.....	Nasal decongestant
Uses	
<ul style="list-style-type: none"> ■ temporarily relieves ■ cough due to inhaled irritants ■ nasal congestion ■ headache ■ sinus congestion and pressure ■ minor aches and pains ■ temporarily 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	
<p>Liver warnings: This product contains acetaminophen. Severe liver damage may occur if you take:</p> <ul style="list-style-type: none"> ■ more than 4,000 mg of acetaminophen in 24 hours ■ with other drugs containing acetaminophen ■ 3 or more alcoholic drinks every day while using this product <p>Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:</p> <ul style="list-style-type: none"> ■ skin redness ■ blisters ■ rash <p>If a skin reaction occurs, stop use and seek medical help right away.</p> <p>Do not use</p> <ul style="list-style-type: none"> ■ 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. <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> ■ liver disease ■ diabetes ■ high blood pressure ■ heart disease ■ thyroid disease ■ trouble urinating due to an enlarged prostate gland 	
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Other information	
<ul style="list-style-type: none"> ■ store between 20-25°C (68-77°F) ■ avoid excessive heat ■ swallow whole; do not crush, chew, or dissolve 	
Inactive ingredients FD&C red #40, FD&C yellow #6, gelatin, glycerin, mannitol, polyethylene glycol, povidone, propylene glycol, purified water, sorbitan, sorbitol, titanium dioxide	
Questions or comments? Call 1-800-935-2382 Monday-Friday 9AM-5PM EST	

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

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KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

PARENTS:
Learn more medicine facts.
www.StopMedicineAbuse.org

NDC 63868-670-16




†Compare to the Active Ingredients in Mucinex® Maximum Strength Sinus-Max® Severe Congestion Relief

Maximum Strength Mucus Relief

Severe Congestion & Sinus

Acetaminophen 325 mg
Dextromethorphan HBr 10 mg
Guaifenesin 200 mg
Phenylephrine HCl 5 mg

Pain Reliever | Cough Suppressant
Expectorant | Nasal Decongestant

Relieves Sinus Congestion
Thins & Loosens Mucus
Relieves Headache
Controls Cough

For Ages 12 Years and Older
Alcohol-Free



actual size

16 Softgels** (**Liquid-Filled Capsules)



Distributed by C.D.M.A., Inc.®
43157 W 9 Mile Rd
Novi, MI 48375
www.qualitychoice.com
Questions: 800-935-2362



PLD-A591A FC005939

Lot No.:
Exp. Date:

QUALITY CHOICE Maximum Strength Mucus Relief Severe Congestion & Sinus

MUCUS RELIEF SEVERE CONGESTION AND SINUS

acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl capsule

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-670
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 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
MANNITOL (UNII: 3OWL53L36A)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
GELATIN (UNII: 2G86QN327L)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	orange	Score	no score
Shape	CAPSULE	Size	20mm
Flavor		Imprint Code	12A
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-670-16	16 in 1 CARTON	06/30/2019	06/30/2025
1		1 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	06/30/2019	06/30/2025

Labeler - QUALITY CHOICE (Chain Drug Marketing Association) (011920774)

Revised: 5/2023

QUALITY CHOICE (Chain Drug Marketing Association)