

**MUCUS RELIEF COLD FLU AND SORE THROAT MAXIMUM STRENGTH-
acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl liquid
Care One (American Sales Company)**

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 20 mL)

Acetaminophen 650 mg

Dextromethorphan HBr 20 mg

Guaifenesin 400 mg

Phenylephrine HCl 10 mg

Purposes

Pain reliever/fever reducer

Cough suppressant

Expectorant

Nasal decongestant

Uses

- temporarily relieves these common cold and flu symptoms:
 - nasal congestion
 - headache
 - sinus congestion and pressure
 - sore throat
 - cough due to minor throat and bronchial irritation
 - minor aches and pains
 - temporarily reduces fever
 - 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

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 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.

Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea or vomiting, consult a doctor promptly.

Do not use

- for children under 12 years of age
- 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.
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

Ask a doctor before use if you have

- diabetes
- liver disease
- heart disease
- thyroid disease
- high blood pressure
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis or emphysema
- cough that occurs with too much phlegm (mucus)
- trouble urinating due to an enlarged prostate gland

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

- redness or swelling is present
- nervousness, dizziness or sleeplessness occur
- new symptoms occur
- pain, nasal congestion or cough gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- 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 (1800-222-1222) 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 6 doses in a 24-hour period
- measure only with dosing cup provided. Do not use any other dosing device
- keep dosing cup with product
- dose as follows or as directed by a doctor
- mL = milliliter
- adults and children 12 years of age and older: 20 mL every 4 hours while symptoms last
- children under 12 years of age: do not use

Other information

- **each 20 mL contains:** sodium 12 mg
- store between 20-25°C (68-77°F). Do not refrigerate.

Inactive ingredients

anhydrous citric acid, disodium EDTA, FD&C blue #1, FD&C red #40, flavor, glycerin, propyl gallate, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol, sucralose, xanthan gum

Principal Display Panel

Compare to the active ingredients in Maximum Strength Mucinex® Fast-Max® Cold, Flu & Sore Throat*

COLD, FLU & SORE THROAT

MUCUS RELIEF

Pain reliever, fever reducer - Acetaminophen

Cough suppressant - Dextromethorphan HBr

Expectorant - Guaifenesin

Nasal decongestant - Phenylephrine HCl

Quick Relief

Relieves Minor Aches & Pains

Reduces Fever

Controls Cough

Clears Nasal & Chest Congestion

Thins & Loosens Mucus

MAXIMUM STRENGTH

FL OZ (mL)

Questions or comments? Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

Distributed by:

Foodhold U.S.A, LLC

Landover, MD 20785

1-877-846-9949

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL AROUND OR UNDER CAP IS BROKEN OR MISSING.

*This product is no manufactured or distributed by Reckitt Benckiser, distributor of Maximum Strength Mucinex® Fast-Max® Cold, Flu & Sore Throat.

Package Label

NDC 41520-036-06

CAREone™

Compare to the Active Ingredients in
Maximum Strength Mucinex®
Fast-Max® Cold, Flu & Sore Throat*

COLD, FLU & SORE THROAT MUCUS RELIEF

Pain Reliever/Fever Reducer - Acetaminophen
Cough Suppressant - Dextromethorphan HBr
Expectorant - Guaifenesin
Nasal Decongestant - Phenylephrine HCl

Quick Relief

Relieves Minor Aches & Pains
Reduces Fever
Controls Cough
Clears Nasal & Chest Congestion
Thins & Loosens Mucus
MAXIMUM STRENGTH



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6 FL OZ
(177mL)

S-949 PLD-B282C LB002486 1016



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or your money back.

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PARENTS:
Learn about teen medicine abuse
www.StopMedicineAbuse.org

PLD-C282C
LB002590

Drug Facts

Active ingredients (in each 20 mL) Purposes

Acetaminophen 650 mg.....Pain reliever/fever reducer
Dextromethorphan HBr 20 mg.....Cough suppressant
Guaifenesin 400 mg.....Expectorant
Phenylephrine HCl 10 mg.....Nasal decongestant

Uses

- temporarily relieves these common cold and flu symptoms
- sinus congestion and pressure
- minor aches and pains
- nasal congestion

PEEL CORNER FOR MORE DRUG FACTS

Drug Facts (continued)

- cough due to minor throat and bronchial irritation
- sore throat
- headache
- temporarily reduces fever
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- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive

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Drug Facts (continued)

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.
- for children under 12 years of age
- 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
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- 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.

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Stop use and ask a doctor if

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Drug Facts (continued)

- 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
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Directions

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- do not take more than 6 doses in any 24-hour period
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Drug Facts (continued)

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PEEL CORNER FOR MORE DRUG FACTS

CAREONE COLD, FLU & SORE THROAT MUCUS RELIEF

MUCUS RELIEF COLD FLU AND SORE THROAT MAXIMUM

STRENGTH

acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-036
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 20 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 20 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg in 20 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 20 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-036-06	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/31/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	10/31/2014	

Labeler - Care One (American Sales Company) (809183973)

Revised: 11/2022

Care One (American Sales Company)