MUCUS RELIEF MAXIMUM STRENGTH SEVERE CONGESTION AND COUGH-
dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride 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)

Dextromethorphan HBr 20 mg

Guaifenesin 400 mg

Phenylephrine HCl 10 mg

Purposes

Cough suppressant

Expectorant

Nasal decongestant

Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
- temporarily relieves:
  - cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants
  - the intensity of coughing
  - the impulse to cough to help you get to sleep
  - nasal congestion due to a cold

Warnings

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.

Ask a doctor before use if you have

- heart disease

- high blood pressure
- thyroid disease
- diabetes
- 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)

When using this product

do not use more than directed.

Stop use and ask a doctor if

- nervousness, dizziness or sleeplessness occur
- symptoms do not get better within 7 days or occur with fever
- 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.

In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

- 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
- mL=milliliter
- shake well before using
- adults and children 12 years of age and older: 20 mL in dosing cup provided every 4 hours
- children under 12 years of age: do not use

Other information

- **each 20 mL contains:** sodium 17 mg
- store between 20-25ºC (68-77ºF). Do not refrigerate.

Inactive ingredients

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® Severe Congestion & Cough*

SEVERE CONGESTION & COUGH

MUCUS RELIEF

Cough Suppressant - Dextromethorphan HBr

Expectorant - Guaifenesin

Nasal Decongestant - Phenylephrine HCl

Quick Relief

Controls Cough,

Clears Nasal & Chest Congestion,

Thins & Loosen Mucus

For Ages 12+

MAXIMUM STRENGTH

FL OZ (mL)

Questions or comments? Call 1-877-753-3935 Mondy-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 not manufactured or distributed by Reckitt Benckiser, distributor of Maximum Strength Mucinex® Fast-Max® Severe Congestion & Cough.

Package Label

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

PLD-C283D
LB003126

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PEEL CORNER FOR MORE DRUG FACTS

Drug Facts (continued)

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Drug Facts (continued)

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Drug Facts (continued)

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CAREONE Mucus Relief Severe Congestion & Cough

MUCUS RELIEF MAXIMUM STRENGTH SEVERE CONGESTION AND COUGH

dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride liquid

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:41520-037
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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:41520-037-06	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)