

**CHEST CONGESTION RELIEF DM- dextromethorphan hydrobromide,
guaifenesin liquid
Major Pharmaceuticals**

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.

Active ingredient (per 5ml teaspoonful)

Dextromethorphan HBr, USP, 10 mg

Guaifenesin, USP 100 mg

Purpose

Cough suppressant

Expectorant

Uses

- temporarily relieves cough due to minor throat and bronchial irritation
- helps loosen phlegm (mucus)
- helps thin bronchial secretions to make coughs more productive

Warnings

Do not use 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.

Do not use if you have ever had an allergic reaction to any of the ingredients in this product.

Ask a doctor before use if you have

- a cough with too much phlegm (mucus)
- a cough that lasts or is chronic such as occurs with smoking asthma, chronic bronchitis or emphysema.

Stop use and ask a doctor if cough lasts more than 7 days, comes back or is accompanied by 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

- take every 4 hours as needed, or as directed by a doctor
- do not take more than 6 doses in 24 hours

- do not exceed recommended dose

Adults and children 12 years and over	2 teaspoonfuls (10 mL)
Children under 12 years	do not use

Inactive ingredients: Cherry flavor, citric acid, FD&C Red #40, menthol, methylparaben, propylene glycol, propylparaben, water, sodium citrate, sucralose, sucrose.

Other Information

- Each teaspoonful (5 mL) contains: sodium 2 mg
- Store at room temperature 15°-30°C (59°-86°F)
- Protect from freezing
- Do not refrigerate
- Protect from light

Pharmacist- Preserve and dispense in a tight, light-resistant container with a child resistant cap as defined in the USP

Distributed By:

MAJOR® PHARMACEUTICAL

Livonia, MI 48152

Refer to package label for Distributor's NDC Number

Guaifenesin Dextromethorphan Oral Solution

100 mg/10 mg per 5mL

Delivers 5 mL



CHEST CONGESTION RELIEF DM

dextromethorphan hydrobromide, guaifenesin liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0904-7134(NDC:0536-1313)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 5 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX25C1OH)	
water (UNII: 059QF0KO0R)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SUCROSE (UNII: C151H8M554)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-7134-70	100 in 1 CASE	10/01/2020	
1		5 mL in 1 CUP; 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	10/01/2020	

Labeler - Major Pharmaceuticals (191427277)

Revised: 9/2022

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