

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

Drug Facts

Active ingredient (per 5mL teaspoonful)

Dextromethorphan HBr, USP 10 mg

Guaifenesin, USP 100 mg

Purpose

Cough suppressant

Expectorant

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

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 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 Pregnancy or Breast Feeding

ask a health professional before use.

Directions

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 teaspoonsfuls (10 mL)
Children under 12 years	do not use

Other Information

- each teaspoon (5 mL) contains: **sodium 2mg**
- 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
- **TAMPER-EVIDENT:** Do not use if foil seal over bottle opening is torn broken or missing.

Inactive Ingredients

cherry flavor, citric acid, FD&C Red #40, menthol, methylparaben, propylene glycol, propylparaben, purified water, sodium citrate, sucralose, sucrose.

Questions

or comments? 1-800-645-2158

This product

is not manufactured or distributed by the owner of the registered trademark Robitussin® DM.

THIS IS A BULK CONTAINER NOT INTENDED FOR DISPENSING.

Distributed by:

RUGBY LABORATORIES

17177 N Laurel Park Drive, Suite 233

Livonia, MI 48152

www.rugbylaboratories.com

Packaged and Distributed by FOR INSTITUTIONAL USE ONLY:

MAJOR® PHARMACEUTICALS

Indianapolis, IN 46268 USA

Refer to package label for Distributor's NDC Number

Questions or comments? 1-800-616-2471

Rev. 08/20	R-164	Re-order No. 371050
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Package/Label Principal Display Panel

MAJOR®

NDC 0904-7135-72

Guaifenesin

Dextromethorphan

Syrup

200 mg/20 mg per 10 mL

Delivers 10 mL

See insert

For Institutional Use Only

Alcohol Free

Cherry Flavor

MAJOR PHARMACEUTICALS

Indianapolis, IN 46268



Principal Display Panel

Product Insert
Guaifenesin
Dextromethorphan Syrup



NDC 0904-7134-70: 10 x 5 mL Unit Dose Cups
 NDC 0904-7135-72: 10 x 10 mL Unit Dose Cups

Drug Facts	
Active ingredient (per 5mL teaspoonful) Purposes	
Dextromethorphan HBr, USP 10 mg	Cough suppressant
Guaifenesin, USP 100 mg	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
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	
Inactive ingredients: cherry flavor, citric acid, FD&C Red #40, methylparaben, propylene glycol, propylparaben, purified water, sodium citrate, sucralose, sucrose	
Questions or comments? 1-800-616-2471	

MAJOR
 MAJOR PHARMACEUTICALS
 Indianapolis, IN 46268

Rev. 08/22

CHEST CONGESTION RELIEF DM
 dextromethorphan hydrobromide, guaifenesin liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0904-7135(NDC:0536-1313)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RT19KYH) (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: Z8IX2SC1OH)	
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:0904-7135-72	100 in 1 CASE	10/01/2020	07/30/2025
1		10 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 Drug	M012	10/01/2020	07/30/2025

Labeler - Major Pharmaceuticals (191427277)