

**CHEST CONGESTION RELIEF DM- dextromethorphan hydrobromide,
guaifenesin liquid
RUGBY LABORATORIES**

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

Dextromethorphan HBr, 10 mg

Guaifenesin 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, 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
 Children under 12 years

2 teaspoonsful (10 mL)
 do not use

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

1-800-645-2158

<p>Drug Facts</p> <p>Active ingredient (per 5mL teaspoonful) Purposes Dextromethorphan HBr, USP 10 mg Cough suppressant Guaifenesin, USP 100 mgExpectorant</p> <p>Uses • temporarily relieves cough due to minor throat and bronchial irritation • helps loosen phlegm (mucus) • helps thin bronchial secretions to make coughs more productive</p> <p>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.</p> <p>Do not use if you have ever had an allergic reaction to any of the ingredients in this product.</p> <p>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</p> <p>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.</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>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. ▶</p>	 <p>NDC 0536-1313-85 Compare to the active ingredients in Robitussin® DM*</p> <h2 style="margin: 0;">Chest Congestion Relief DM</h2> <h3 style="margin: 0;">Oral Solution</h3> <p>Guaifenesin Dextromethorphan Expectorant Cough Suppressant</p> <p>Cherry Flavored</p> <ul style="list-style-type: none"> - Controls Cough - Loosens and Relieves Chest Congestion - Alcohol Free <p>Cough Formula for Adults and Children 12 Years and Over</p> <div style="background-color: #e67e22; color: white; padding: 5px; display: inline-block; font-weight: bold;">16 FL OZ (473 mL)</div> <p style="background-color: #e67e22; color: white; padding: 2px; display: inline-block; font-weight: bold;">PACKAGE NOT CHILD RESISTANT</p>	<p>Drug Facts (continue)</p> <p>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</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 70%;">Adults and children 12 years and over</td> <td>2 teaspoonsful (10 mL)</td> </tr> <tr> <td>Children under 12 years</td> <td>do not use</td> </tr> </table> <p>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 • TAMPER-EVIDENT: Do not use if foil seal over bottle opening is torn broken or missing.</p> <p>Inactive ingredients: cherry flavor, citric acid, FD&C Red #40, menthol, methylparaben, propylene glycol, propylparaben, purified water, sodium citrate, sucralose, sucrose.</p> <p>Questions or comments? 1-800-645-2158</p> <p><small>*This product is not manufactured or distributed by the owner of the registered trademark Robitussin® DM.</small></p> <p><small>THIS IS A BULK CONTAINER NOT INTENDED FOR DISPENSING.</small></p> <p><small>Rev. 08/20 R-164 Re-order No. 371050</small></p> <p><small>Distributed by: RUGBY® LABORATORIES 7177 N Laurel Park Drive, Suite 233 Livonia, MI 48152 www.rugbylaboratories.com</small></p> <div style="text-align: center;">  <small>3 05361 31385 2</small> </div> <p style="text-align: right;"><small>Code# L73 Lot# Exp. Date: REV0820</small></p>	Adults and children 12 years and over	2 teaspoonsful (10 mL)	Children under 12 years	do not use
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CHEST CONGESTION RELIEF DM

dextromethorphan hydrobromide, guaifenesin liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	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 (UNII: L7T10EIP3A)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
water (UNII: 059QF0KO0R)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SUCROSE (UNII: C151H8M554)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-1313-85	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	10/01/2020	

Labeler - RUGBY LABORATORIES (079246066)

Revised: 3/2022

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