

MUCOLYTE DM- guaifenesin, dextromethorphan hbr liquid
Rising Pharma Holdings, Inc.

Mucolyte-DM
Guaifenesin-Dextromethorphan HBr

Drug Facts

Active Ingredients (in each 5 mL teaspoonful)

Guaifenesin, USP 100 mg

Dextromethorphan Hydrobromide, USP 10 mg

Purposes

Expectorant

Cough Suppressant

Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive
- temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold

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

- cough that occurs with too much phlegm (mucus)
- 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 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. In case of overdose, get medical help or contact a Poison Control Center 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

- store at 20°-25°C (68°-77°F)
- protect from freezing
- protect from light
- do not refrigerate
- **TAMPER-EVIDENT:** Do not use if foil seal over bottle is torn, broken or missing
- **Pharmacist:** Preserve and dispense in tight, light-resistant container with a child resistant cap as defined in the USP

Inactive Ingredients

Cherry flavor, citric acid, FD&C Red #40, glycerin, menthol, propylene glycol, sodium benzoate, sodium citrate dihydrate, sodium saccharin, sorbitol, sucralose, water.

Questions or comments

Call 1-844-474-7464

*This product is neither manufactured nor distributed by the owner of the registered trademark Robitussin®-DM

MUCOLYTE-DM™ is a trademark owned by Rising Pharma Holdings, Inc.

Distributed by:

Rising Pharma Holdings, Inc.
East Brunswick, NJ 08816

NDC 57237-360-16

Mucolyte-DM™**Guaifenesin -
Dextromethorphan HBr****100mg/10mg per 5mL****Expectorant/Cough
Suppressant**

Compare to the active ingredients in Robitussin®-DM*

- ✔ Controls Cough
- ✔ Loosens and Relieves Chest Congestion
- ✔ Alcohol free
- ✔ Sugar free

**16 fl.oz. (473 mL)****CHERRY
FLAVOR****Drug Facts**

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 Dextromethorphan Hydrobromide, USP 10 mg.....Cough Suppressant

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Drug Facts (continued)

- protect from light
- do not refrigerate
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Issued: 12/2025

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LOT:
EXP:

**MUCOLYTE DM**

guaifenesin, dextromethorphan hbr liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57237-360
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID (UNII: 2968PHW8QP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
MENTHOL (UNII: L7T10EIP3A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SODIUM SACCHARIN (UNII: SB8ZUX40TY)	

SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3Z D4)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57237-360-12	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/22/2025	
2	NDC:57237-360-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/22/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	12/22/2025	

Labeler - Rising Pharma Holdings, Inc. (116880195)

Registrant - Invahealth Inc. (116840615)

Establishment

Name	Address	ID/FEI	Business Operations
Invahealth Inc.		116840615	manufacture(57237-360) , analysis(57237-360)