

MUCOLYTE- guaifenesin liquid
Rising Pharma Holdings, Inc.

Mucolyte
Guaifenesin Liquid USP

Drug Facts

Active Ingredient (in each 5mL)

Guaifenesin, USP 100 mg

Purpose

Expectorant

Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive.

Warnings

Do not use

- if you 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

- Do not take more than 6 doses in a 24-hour period
- Do not exceed recommended dose

adults and children 12 years and over	2 to 4 teaspoonfuls (10mL to 20mL) every 4 hours
children under 12 years	ask a doctor

Other Information

MUCOLYTE
guaifenesin liquid

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57237-359	
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	
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 (UNII: 1Q73Q2JULR)				
SODIUM SACCHARIN (UNII: SB8ZUX40TY)				
SORBITOL (UNII: 506T60A25R)				
SUCRALOSE (UNII: 96K6UQ3ZD4)				
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:57237-359-12	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/22/2025	
2	NDC:57237-359-16	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(57237-359) , analysis(57237-359)

Revised: 12/2025

Rising Pharma Holdings, Inc.