

ROBITUSSIN MUCUS PLUS CHEST CONGESTION- guaifenesin liquid

Richmond Division of Wyeth

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.

ROBITUSSIN® MUCUS PLUS CHEST CONGESTION

Drug Facts

Active ingredient (in each 10 mL)

Guaifenesin, USP 200 mg

Purpose

Expectorant

Use

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

Warnings

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 any 24-hour period
- measure only with dosing cup provided
- keep dosing cup with product
- ml=milliliter
- this adult product is not intended for use in children under 12 years of age

age	dose
adults and children 12 years and over	10-20 ml every 4 hours
children under 12 years	do not use

Other information

- **each 10 ml contains:** sodium 4 mg
- store at 20-25°C (68-77°F). Do not refrigerate

- alcohol-free

Inactive ingredients

anhydrous citric acid, artificial flavor, caramel, FD&C red no. 40, glycerin, high fructose corn syrup, liquid glucose, menthol, propylene glycol, purified water, saccharin sodium, sodium benzoate

Questions or comments?

Call weekdays from 9 AM to 5 PM EST at **1-800-762-4675**

Distributed by:

Pfizer, Madison, NJ 07940 USA

For most recent product information, visit www.robitussin.com

PRINCIPAL DISPLAY PANEL - 118 mL Bottle Label

ADULT

Robitussin®

Mucus + Chest Congestion

GUAIFENESIN (Expectorant)

Alcohol-Free

4 FL OZ (118 ml)

**Packaged with Tamper-Evident bottle cap.
Do Not Use if breakable ring is separated or missing.**

Active ingredient (in each 10 ml):
Guaifenesin, USP 200 mg

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

Warnings
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.
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LOT: _____
EXP: _____

PAA035209

PRINCIPAL DISPLAY PANEL - 118 mL Bottle Carton

ADULT

Robitussin®

**Mucus + Chest
Congestion**

GUAIFENESIN (Expectorant)

guaifenesin liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0031-8724
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 10 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
CAMEL (UNII: T9D99G2B1R)	
DEXTROSE (UNII: IY9XDZ35W2)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
PROPYLENE GLYCOL, (R)- (UNII: 602HN5L69H)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	

Product Characteristics

Color	RED (deep wine)	Score	
Shape		Size	
Flavor	RASPBERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0031-8724-12	1 in 1 CARTON		
1		118 mL in 1 BOTTLE; 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	07/18/2012	

Labeler - Richmond Division of Wyeth (829390835)

Establishment

Name	Address	ID/FEI	Business Operations
Fareva Richmond, Inc.		969523245	ANALYSIS(0031-8724) , LABEL(0031-8724) , MANUFACTURE(0031-8724) , PACK(0031-8724) , RELABEL(0031-8724) , REPACK(0031-8724)

Revised: 3/2015

Richmond Division of Wyeth