

RITUSSIN EXPECTORANT- guaifenesin liquid
Rij Pharmaceutical Corporation

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.

Drug Facts

Active ingredient (in each 5 mL)(one teaspoonful)

Guaifenesin, USP 100 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

age	dose
adults and children 12 years of age and over	2-4 teaspoons every 4 hours
children 6 years to under 12 years of age	1-2 teaspoonful every 4 hours
children 2 years to under 6 years of age	1/2-1 teaspoonful every 4 hours
children under 2 years of age	ask a doctor

Other information

- store at room temperature 15° - 30°C (59° - 86°F)
- protect from freezing.

- protect from light.
- Each teaspoon (5 mL) contains: sodium 2 mg.
- **TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF BREAKAWAY BAND ON CAP IS BROKEN OR MISSING**

Inactive ingredients

caramel, citric acid, FD&C Red #40, , flavors, glucose, glycerin, high fructose corn syrup, menthol, propylene glycol, sodium saccharin, sodium benzoate, water

PRINCIPAL DISPLAY PANEL

NDC 53807-408-16



RITUSSIN

Expectorant

(Guaifenesin Syrup)

Loosens & Relieves Chest Congestion

This is a bulk package. Dispense contents with a child-resistant closure in a tight, light resistant container as defined in the USP.

ALCOHOL FREE

Children & Adults Cough Formula

16 Fl. oz. (473 mL)

Drug Facts

Active ingredient (in each 5ml)(one teaspoonful)	Purpose
Guaifenesin, USP 100 mg	Expectorant

Uses ▪ 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.

age	dose
adults and children 12 years of age and over	2-4 teaspoonfuls every 4 hours
children 6 years to under 12 years of age	1-2 teaspoonful every 4 hours
children 2 years to under 6 years of age	1/2-1 teaspoonful every 4 hours
under 2 years of age	ask a doctor

Other information ▪ store at room temperature 15° - 30°C (59° - 86°F)
 ▪ protect from freezing ▪ protect from light
 ▪ Each teaspoon (5 mL) contains: sodium 2 mg.

TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF BREAKAWAY BAND ON CAP IS BROKEN OR MISSING.

Inactive ingredients: caramel, citric acid, FD&C Red #40, flavors, glucose, glycerin, high fructose corn syrup, menthol, sodium saccharin, sodium benzoate, water.

†This product is not manufactured or distributed by the owner of the registered trademark Robitussin®.

RIJ PHARMACEUTICAL CORPORATION
 40 COMMERCIAL AVENUE
 MIDDLETOWN, NY 10941

Rev. 06/12



N 3 53807 - 40816 7

guaifenesin liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53807-408
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
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 (UNII: L7T10EIP3A)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	

Product Characteristics

Color	RED	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53807-408-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/16/1999	
2	NDC:53807-408-08	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/16/1999	
3	NDC:53807-408-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/16/1999	
4	NDC:53807-408-28	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/16/1999	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	03/16/1999	

Labeler - Rij Pharmaceutical Corporation (144679156)

Establishment

Name	Address	ID/FEI	Business Operations
Rij Pharmaceutical Corporation		144679 156	manufacture(53807-408)

Revised: 4/2018

Rij Pharmaceutical Corporation