

COUGH- guaifenesin liquid
Rebel Distributors Corp

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.

Rugby®
Cough
SYRUP

Active ingredient (in each 5 mL teaspoonful)

Guaifenesin 100 mg

Uses

helps loosen phlegm and thin bronchial secretions to rid the bronchial passageways of bothersome mucus

Warnings

Ask a doctor before use if you have

- a cough with too much phlegm (mucus)
- a persistent or chronic cough 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 occurs with 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 right away.

Directions

- take every four hours
- do not take more than 6 doses in 24 hours

adults and children 12 years and over	2–4 teaspoonfuls
children 6 to under 12 years	1–2 teaspoonfuls
children under 6 years	do not use

Other information

- **each teaspoonful contains:** sodium 3 mg
- store at room temperature 15°–30°C (59°–86°F)

Inactive ingredients

caramel powder, citric acid, corn syrup, FD&C red #40, glycerin, menthol, propylene glycol, purified water, saccharin sodium, sodium benzoate

1-800-645-2158, 9 am – 5 pm ET, Monday – Friday

TAMPER EVIDENT

DO NOT USE IF INNER FOIL SEAL OVER MOUTH OF BOTTLE IS BROKEN OR MISSING

PRINCIPAL DISPLAY PANEL - 118 mL Bottle Label

Rebel Distributors Corp

NDC 21695-705-04

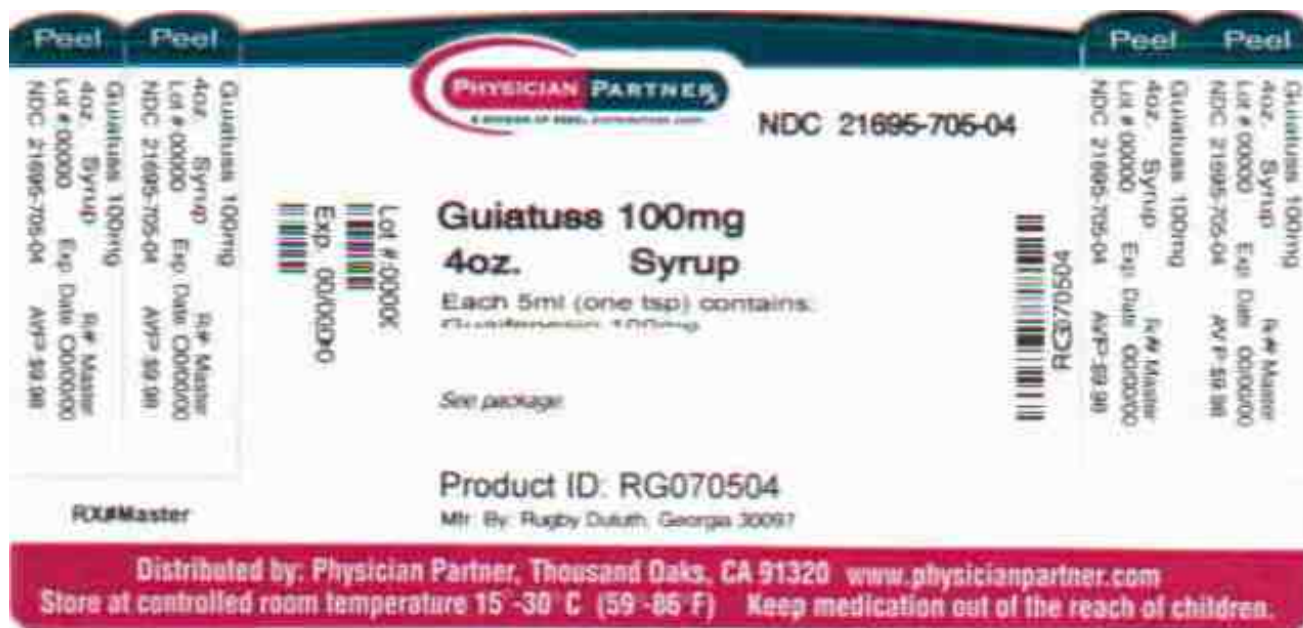
- FOR ADULTS AND CHILDREN
- NON-NARCOTIC EXPECTORANT
- ALCOHOL FREE

Cough

SYRUP

Guaifenesin, USP

4 fl oz (118 mL)



COUGH

guaifenesin liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21695-705(NDC:0536-0825)
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
Caramel (UNII: T9D99G2B1R)	
Citric Acid Monohydrate (UNII: 2968PHW8QP)	
Corn Syrup (UNII: 9G5L16BK6N)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
Glycerin (UNII: PDC6A3C0OX)	
Menthol (UNII: L7T10EIP3A)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Water (UNII: 059QF0KO0R)	
Sodium Benzoate (UNII: OJ245FE5EU)	
Saccharin Sodium (UNII: SB8ZUX40TY)	

Product Characteristics

Color	PINK (Reddish-Pink)	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21695-705-04	118 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	12/04/2009	

Labeler - Rebel Distributors Corp (118802834)

Establishment

Name	Address	ID/FEI	Business Operations
Rebel Distributors Corp		118802834	RELABEL, REPACK

Revised: 2/2011

Rebel Distributors Corp