RUGBY COUGH GUAIFENESIN- guaifenesin liquid
Unit Dose Services

Rugby Cough SYRUP Guaifenesin, 4 fl oz (118 mL)

Drug Facts

Active ingredient (in each 10 mL)

Guaifenesin, USP 200 mg

Purpose

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 last 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 at 1-800-222-1222.

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 mL-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).
- alcohol-free

Inactive ingredients

citric acid, disodium edetate , FD&C red no. 40, flavors, potassium citrate, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, xanthan gum.

Questions?

1-866-467-2748

Distributed by:
Rugby Laboratories

31778 Enterprise Drive

Livonia, MI 48150

www.rugbylaboratories.com

Re-order No.370448

Rev.10/15

R-107

HOW SUPPLIED

Product: 50436-1095

NDC: 50436-1095-1 1 mL in a CARTON / 118 in a BOTTLE

RUGBY COUGH SYRUP GUAIFENESIN (GUAIFENESIN) LIQUID

NDC: 50436-1095-1
GUAIFENESIN, USP COUGH SYRUP
4 fl oz (118 mL)

• FOR AGES 12 AND OVER • ALCOHOL-FREE
• NON-NARCOTIC EXPECTORANT

Rev. 1

Pkg by: Unit Dose Services, LLC Dania, FL 33004 Dist by: Rugby Laboratories Livonia, MI 48152

DRUG FACTS Active Ingredient (in each 10 mL) **Purpose**
Guaifenesin, USP 200mg 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 last 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 healthcare professional before use. **Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away at 1-800-222-1222.

Inactive Ingredients: citric acid, disodium edetate, FD&C red no. 40, flavors, potassium citrate, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, xanthan gum

Other Information: • Each 10 mL contains: sodium 4 mg • Store at 20-25° C (68-77° F) • Alcohol-free

Directions: • Do not take more than 6 doses in 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
• **Adults and children 12 years and over:** 10 mL - 20 mL every 4 hours
• **Children under 12 years:** do not use

MFG NDC: 0536-1095-97
MFG LOT: XXXXXX
SERIAL: XXXXX000003
LOT: XXXXX EXP: XX/XX/XX

NDC: 50436-1095-1
DRUG: GUAIFENESIN, USP COUGH SYRUP
4 fl oz (118 mL)
LOT: XXXXX EXP: XX/XX/XX

NDC: 50436-1095-1
DRUG: GUAIFENESIN, USP COUGH SYRUP
4 fl oz (118 mL)
LOT: XXXXX EXP: XX/XX/XX

NDC: 50436-1095-1
DRUG: GUAIFENESIN, USP COUGH SYRUP
4 fl oz (118 mL)
LOT: XXXXX EXP: XX/XX/XX

RUGBY COUGH GUAIFENESIN

guaifenesin liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50436-1095(NDC:0536-1095)
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)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
POTASSIUM CITRATE (UNII: EE90ONI6FF)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics			
Color	RED	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:50436-1095-1	118 in 1 BOTTLE	01/08/2019	
1		1 mL in 1 CARTON; 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	04/20/2016	

Labeler - Unit Dose Services (831995316)

Establishment

Name	Address	ID/FEI	Business Operations
Unit Dose Services		831995316	REPACK(50436-1095) , RELABEL(50436-1095)