

ROBAFEN COUGH FORMULA- guaifenesin syrup
REMEDYREPACK INC.

Reference Label Set Id: f69efbaf-a1ee-49c5-af2d-b1f3bb468d62

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.

Robafen™ Syrup

Drug Facts

Active ingredient (in each 2 TSP (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

- a persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis or emphysema
- a cough occurs with too much phlegm (mucus)

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 the 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
- this product is not intended for use in children under 12 years of age
- TSP = teaspoonful

adults and children 12 years and over	2 - 4 TSP every 4 hours
children under 12 years	do not use

Other information

- each TSP (5 mL) contains: **sodium 3 mg**
- store at 20°-25°C (68°-77°F). Do not refrigerate.

Inactive ingredients

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

Questions or comments?

(800) 616-2471

Distributed by

MAJOR[®] PHARMACEUTICALS

17177 N Laurel Park Drive, Suite 233,

Livonia, MI 48152

DRUG: ROBAFEN COUGH FORMULA

GENERIC: Guaifenesin

DOSAGE: SYRUP

ADMINISTRATION: ORAL

NDC: 61786-963-45

COLOR: brown

FLAVOR: MENTHOL

PACKAGING: 118 mL in 1 BOTTLE

ACTIVE INGREDIENT(S):

- Guaifenesin 100mg in 5mL

INACTIVE INGREDIENT(S):

- Corn Syrup
- FD&C Red no. 40
- Menthol, Unspecified Form
- Caramel
- Water
- Glycerin
- Sodium Benzoate
- Propylene Glycol
- Anhydrous Citric Acid
- Saccharin Sodium

Robafen Cough Formula

Guaifenesin

100 mg/5 mL Syrup

QTY: **118**

ID #: .

Expires:

NDC #: 61786-0963-45

Shape: .

LOT #:

Ref #: 00904-0061-00

MFG: Major Pharma, Livonia, MI 48150

NOT FOR RETAIL SALE

Directions For Use: See Package Insert

Store at 20-25°C (68-77°F); excursions permitted to 15-30°C (59-86°F) [See USP]

Repackaged by:

RemedyRepack Inc., Indiana, PA 15701, 1-724-465-8762



ROBAFEN COUGH FORMULA

guaifenesin syrup

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61786-963(NDC:0904-0061)
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
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
CORN SYRUP (UNII: 9G5L16BK6N)	
WATER (UNII: 059QF0KO0R)	

CARAMEL (UNII: T9D99G2B1R)

FD&C RED NO. 40 (UNII: WZB9127XOA)

Product Characteristics

Color	brown (Reddish-Brown)	Score	
Shape		Size	
Flavor	MENTHOL	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61786-963-45	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/31/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	10/31/2016	

Labeler - REMEDYREPACK INC. (829572556)

Revised: 10/2017

REMEDYREPACK INC.