# ROBAFEN COUGH FORMULA- guaifenes in syrup Aidarex Pharmaceuticals LLC

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.

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#### **ROBAFEN™ COUGH FORMULA**

#### **Drug Facts**

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

Guaifenesin USP 100 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 cough that lasts or a chronic cough such as occurs with smoking, asthma, chronic bronchitis or emphysema
- cough occurs with too much phlegm (mucus)

**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 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

addins and children 12 years and over	2 - 4 teaspoons every 4 hours or as directed by a doctor
children under 12 years	do not use

#### Other information

- each teaspoonful (5 mL) 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, sodium benzoate, sodium saccharin

## Questions?

Adverse Drug Event Call: (800) 616-2471

Distributed by MAJOR PHARMACEUTICALS

31778 Enterprise Drive Livonia, MI 48150 USA

Repackaged By : Aidarex Pharmaceuticals LLC, Corona, CA 92880

#### PRINCIPAL DISPLAY PANEL

NDC 53217-0024-01 TAMPER-EVIDENT

Robafen™ Syrup

(brand of Guaifenesin syrup USP 100 mg per 5 mL)

**EXPECTORANT** 

## Each teaspoonful (5 mL) contains:

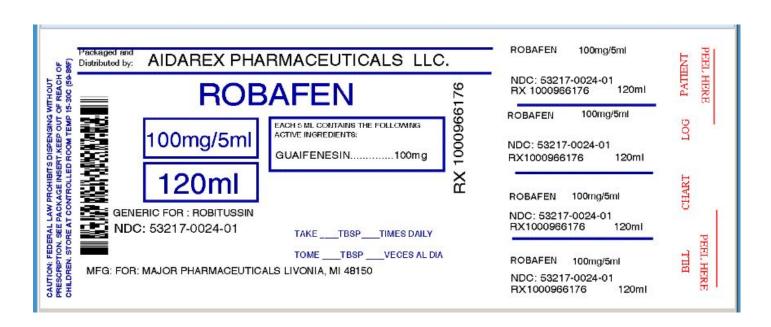
Guaifenesin (Glyceryl Guaiacolate), USP 100 mg

TAMPER-EVIDENT: Do not use this product if inner foil seal over the mouth of the bottle is cut, torn, broken or missing.

For Dispensing Purpose Only

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## **ROBAFEN COUGH FORMULA**

guaifenesin syrup

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:53217-024(NDC:0904-0061)

Route of Administration ORAL

## Active Ingredient/Active Moiety

	3	3			
		Ingredient Name		<b>Basis of Strength</b>	Strength
GU	J <b>aifenesin</b> (Uni	I: 495W7451VQ) (GUAIFENESIN - UNII:495W7	(451VQ)	GUAIFENESIN	100 mg in 5 mL

Inactive Ingredients		
Ingredient Name	Strength	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY)		
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)		
GLYCERIN (UNII: PDC6 A3C0 OX)		
MENTHOL (UNII: L7T10 EIP3A)		
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:53217-024-01	118 mL in 1 BOTTLE, PLASTIC		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH FINAL	part341	08/15/2012		

## Labeler - Aidarex Pharmaceuticals LLC (801503249)

Revised: 10/2013 Aidarex Pharmaceuticals LLC