

**ROBAFEN COUGH FORMULA- guaifenesin 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

adults 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**

Distributed by

**MAJOR PHARMACEUTICALS**

31778 Enterprise Drive

Livonia, MI 48150 USA

Repackaged By :

Aidarex Pharmaceuticals LLC,

Corona, CA 92880

Packaged and Distributed by: **AIDAREX PHARMACEUTICALS LLC.**  
**ROBAFEN**  
**100mg/5ml**  
**120ml**  
 EACH 5 ML CONTAINS THE FOLLOWING ACTIVE INGREDIENTS:  
 GUAIFENESIN.....100mg  
 RX 1000966176  
 NDC: 53217-0024-01  
 RX 1000966176 120ml  
 ROBAFEN 100mg/5ml  
 NDC: 53217-0024-01  
 RX1000966176 120ml  
 ROBAFEN 100mg/5ml  
 NDC: 53217-0024-01  
 RX1000966176 120ml  
 ROBAFEN 100mg/5ml  
 NDC: 53217-0024-01  
 RX1000966176 120ml  
 CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT. KEEP OUT OF REACH OF CHILDREN. STORE AT CONTROLLED ROOM TEMP 15-30C (59-86F)  
 GENERIC FOR : ROBITUSSIN  
 NDC: 53217-0024-01  
 TAKE \_\_\_ TBSP \_\_\_ TIMES DAILY  
 TOME \_\_\_ TBSP \_\_\_ VECES AL DIA  
 MFG: FOR: MAJOR PHARMACEUTICALS LIVONIA, MI 48150  
 PEEL HERE  
 PATIENT LOG CHART  
 PEEL HERE  
 BILL TTB

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			
	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 (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: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