

**ROBAFEN- guaifenesin solution**  
**Major Pharmaceuticals**

*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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**Major Pharmaceuticals Robafen™ Drug Facts**

**Active ingredient (in each 10 mL)**

Guaifenesin, USP 200 mg

**Purpose**

Expectorant

**Use**

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 lasts for more than 7 days, comes back, or is accompanied by fever, rash, or persistent headache. A persistent cough may be a sign 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 (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 - 20 mL every 4 hours
children under 12 years	do not use

### Other information

- store at 20-25°C (68-77°F). Do not refrigerate.

### Inactive ingredients

anhydrous citric acid, caramel, FD&C red no. 40, flavor, glycerin, high fructose corn syrup, menthol, propylene glycol, purified water, saccharin sodium, sodium benzoate

### Questions or comments?

**1-800-616-2471**

### Principal Display Panel

ROBAFEN™

Congestion Formula

Guaifenesin, USP 200 mg

Expectorant

Relieves:

Mucus

Chest Congestion

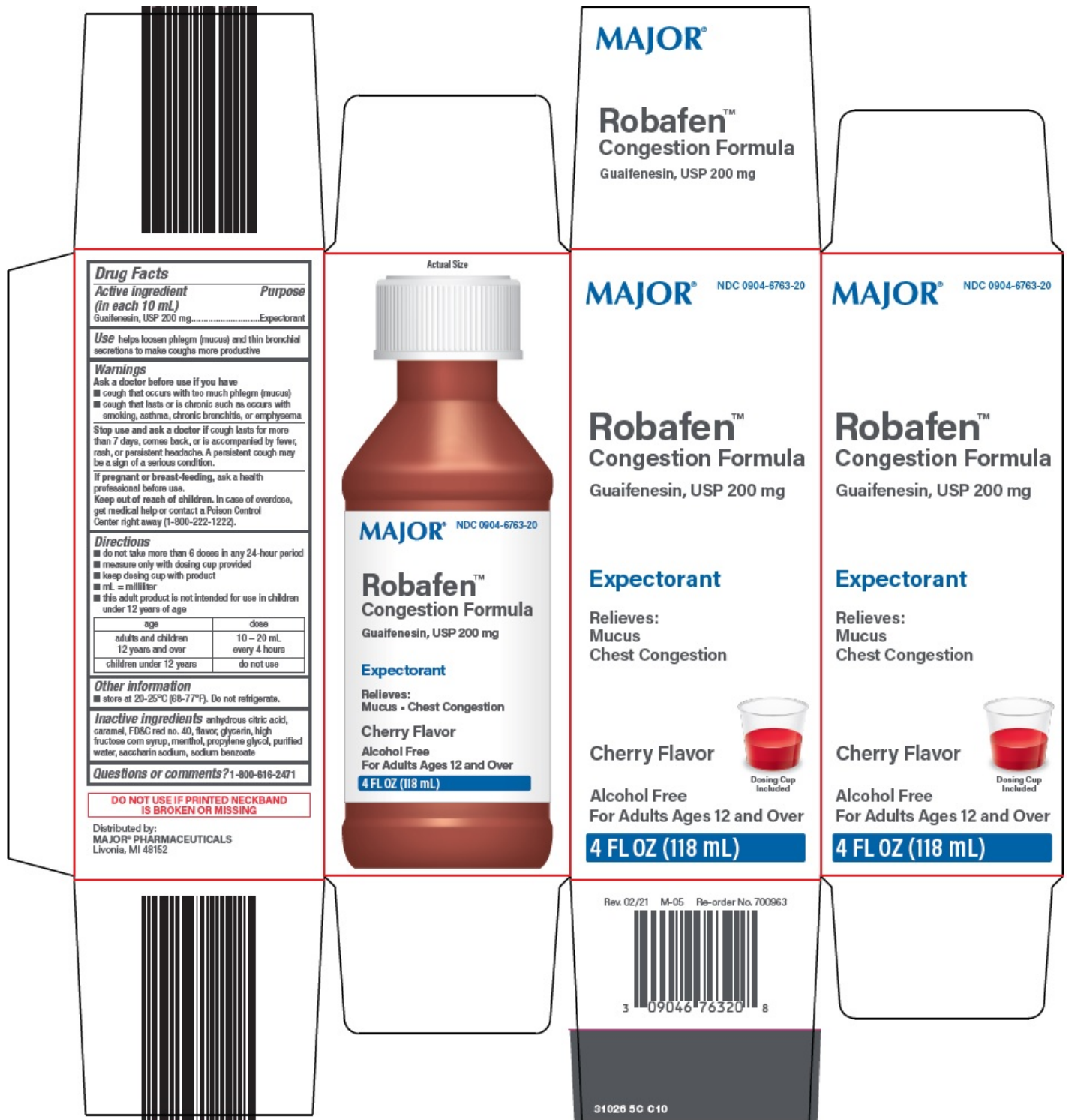
Cherry Flavor

Dosing Cup Included

Alcohol Free

For Adults Ages 12 and Over

4 FL OZ (118 mL)



**ROBAFEN**  
 guaifenesin solution

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0904-6763
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 10 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>CARAMEL</b> (UNII: T9D99G2B1R)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>HIGH FRUCTOSE CORN SYRUP</b> (UNII: XY6UN3QB6S)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>MENTHOL, UNSPECIFIED FORM</b> (UNII: L7T10EIP3A)	

**Product Characteristics**

<b>Color</b>	RED (dark)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	CHERRY	<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-6763-20	1 in 1 CARTON	08/13/2018	
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0904-6763-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/10/2018	02/28/2022

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	08/13/2018	

**Labeler** - Major Pharmaceuticals (191427277)