

ROBAFEN- guaifenesin solution
A-S Medication Solutions

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.

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, maltol, menthol, propylene glycol, purified water, saccharin sodium, sodium benzoate

Questions or comments?

1-800-616-2471

HOW SUPPLIED

Product: 50090-4189

NDC: 50090-4189-0 473 mL in a BOTTLE

Guaifenesin



ROBAFEN

guaifenesin solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50090-4189(NDC:0904-6763)
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)	
CARAMEL (UNII: T9D99G2B1R)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
MALTOL (UNII: 3A9RD92BS4)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	

Product Characteristics

Color	RED (dark)	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50090-4189-0	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/14/2019	

Marketing Information

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

Labeler - A-S Medication Solutions (830016429)

Establishment

Name	Address	ID/FEI	Business Operations
A-S Medication Solutions		830016429	RELABEL(50090-4189)

Revised: 4/2021

A-S Medication Solutions