GUAIFENESIN- guaifenesin liquid
Method 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.

Guaifenesin

NDC 58657-509-16

Guaifenesin

Liquid USP

100 mg/5 Ml

Expectorant

Sugar Free • Alcohol Free

Cherry Flavor

Loosens and Relieves Chest Congestion

16 fl. oz. (473 mL)

Drug Facts

Active ingredient (in each 5 mL)

Guaifenesin 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

- 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 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 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
  age dose adults and children 2 to 4 teaspoonfuls
  12 years and over every 4 hours
  children 6 years to 1 to 2 teaspoonfuls
  under 12 years every 4 hours
  children 2 years to ½ to 1 teaspoonful
  under 6 years every 4 hours
  children under 2 years ask a doctor

Drug Facts (continued)

Other information

- store at 20°-25°C (68°-77°F)
- packaged with tamper evident seal under cap

Inactive ingredients

Bitter Mask, Cherry Flavor, Citric Acid, FD&C Red#40, Glycerin, Propylene Glycol, Purified Water, Sodium Benzoate, Sodium Citrate, Sodium Saccharin, Sorbitol Solution

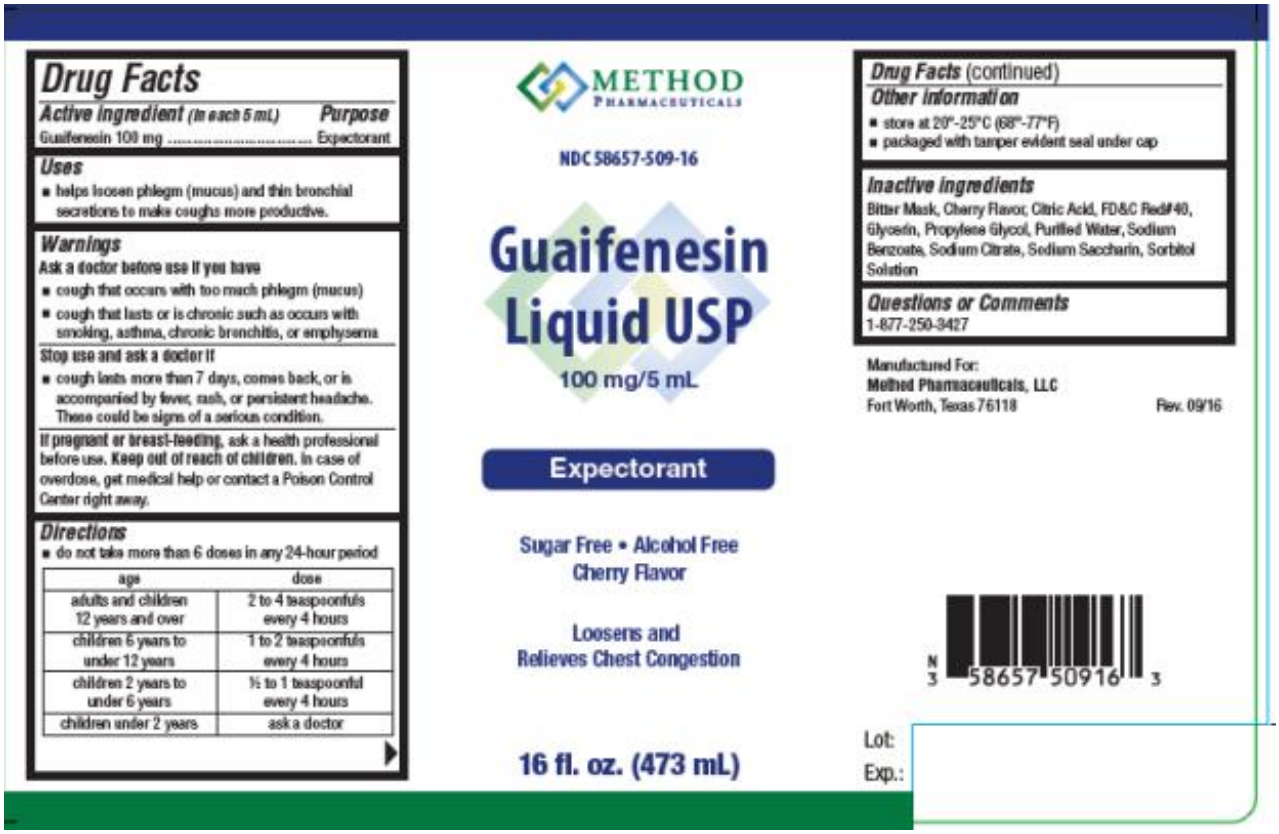
Questions or Comments

1-877-250-3427

Manufactured For:
Method Pharmaceuticals, LLC
Fort Worth, Texas 76118 Rev. 09/16

PRINCIPAL DISPLAY PANEL

NDC 58657- 509- 16
Guaifenesin
Liquid USP
100 mg/ 5 mL
Expectorant
16 fl. oz. (473 mL)



GUAIFENESIN

guaifenesin liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58657-509
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**
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics			
Color	red	**Score**	
Shape		**Size**	
Flavor	CHERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58657-509-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/09/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	02/09/2016	

Labeler - Method Pharmaceuticals, LLC (060216698)

Establishment

Name	Address	ID/FEI	Business Operations
Monarch PCM, LLC		080000294	manufacture(58657-509)

Revised: 12/2021 Method Pharmaceuticals, LLC