GUAIFENESIN AND DEXTROMETHORPHAN HYDROBROMIDE- guaifenesin and dextromethorphan hydrobromide syrup
Method Pharmaceuticals

Guaifenesin and Dextromethorphan Hydrobromide Syrup

Active ingredients

Dextromethorphan HBr, USP 10 mg
Guaifenesin, USP 100 mg

Purpose

Cough suppressant
Expectorant

Uses

- temporarily relieves cough due to minor throat and bronchial irritation
- helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive

Warnings

Do not use if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

- persistent cough or chronic cough such as occurs with smoking, asthma, chronic bronchitis, emphysema
- cough accompanied by excessive phlegm (mucus)

Stop use and ask a doctor if

- cough lasts more than 7 days or occurs with fever, rash, or headaches that lasts. This could be a sign of a serious condition
- hypersensitive to any ingredients

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. **This adult product is not intended for use in children under 12 years of age**

adults and children 12 years and over	2 teaspoonfuls (TSP) every 4 hours
children 6 to 12 years of age	1 teaspoonful (TSP) every 4 hours
children under 6 years	**DO NOT USE**

TAMPER-EVIDENT

Do not use if seal cap is broken or missing.

Inactive ingredients

Anhydrous citric acid, dextrose, FD&C Red #40, flavor, gylcerin, high fructose corn syrup, menthol, purified water, saccharin sodium, sodium benzoate

Other information

- store at room temperature 20°-25°C (68°-77°F)
- **each 5 mL contains:** sodium 3 mg

Questions

1-877-250-3427

Principal Display Panel

Method Pharmaceuticals

NDC 58657-504-08

Guaifenesin and Dextromethorphan Hydrobromide Syrup

100 mg/10 mg/5 mL

Expectorant

Cough Suppressant

Grape Flavor

Non Drowsy • Alcohol Free

FOR AGES 12 AND UP

8 fl. oz. (237 mL)

Manufactured For:

Method Pharmaceuticals, LLC

Southlake, TX 76092 Rev. 02/2024

GUAIFENESIN AND DEXTROMETHORPHAN HYDROBROMIDE

guaifenesin and dextromethorphan hydrobromide syrup

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58657-504
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 5 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
MENTHOL (UNII: L7T10EIP3A)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
DEXTROSE (UNII: IY9XDZ35W2)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	

Product Characteristics			
Color		**Score**	
Shape		**Size**	
Flavor	GRAPE	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:58657-504-08	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/01/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	04/01/2024	

Labeler - Method Pharmaceuticals (060216698)

Revised: 4/2024 Method Pharmaceuticals