

GUAIFENESIN AND DEXTROMETHORPHAN HYDROBROMIDE- guaifenesin and dextromethorphan hydrobromide syrup

Method 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.

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 under 12 years	DO NOT USE

Inactive ingredients

Citric Acid Anhydrous, USP; Sodium Citrate Dihydrate, USP; Sodium Saccharin, USP; Propylene Glycol, USP; Grape Flavor; Sorbitol Solution, USP; Glycerin, USP; Maltitol Solution, NF

Other information

- store at room temperature 20°-25°C (68°-77°F)

Questions

1-877-250-3427

Principal Display Panel

Method Pharmaceuticals

NDC 58657-505-08

Guaifenesin and Dextromethorphan Hydrobromide Syrup

100 mg/10 mg/5 mL

Expectorant

Cough Suppressant

Grap Flavor

Non Drowsy • Alcohol Free

FOR AGES 12 AND UP

8 fl. oz. (237 mL)

Manufactured For:

Method Pharmaceuticals, LLC

Fort Worth, TX 76118 Rev. 06/2016



NDC 58657-505-08

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100 mg/10 mg/5 mL

Expectorant Cough Suppressant

Grape Flavor

Non Drowsy • Alcohol Free

FOR AGES 12 AND UP

8 fl. oz. (237mL)

Drug Facts

Active ingredient (in each 5 mL) Purpose
 Dextromethorphan Hydrobromide 10 mg Cough Suppressant
 Guaifenesin 100 mg 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.

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Drug Facts (continued)

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 under 12 years	DO NOT USE

Inactive ingredients

Citric Acid Anhydrous, USP; Glycerin, USP; Grape Flavor; Maltitol Solution, NF; Propylene Glycol, USP; Purified Water; Sodium Citrate Dihydrate, USP; Sodium Saccharin, USP; Sorbitol Solution, USP

Other information

- store at room temperature 20°-25°C (68°-77°F)

Questions 1-877-250-3427

Manufactured For:
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Lot: Exp.:

GUAIFENESIN AND DEXTROMETHORPHAN HYDROBROMIDE

guaifenesin and dextromethorphan hydrobromide syrup

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58657-505
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9 D2RTI9 KYH) (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)	
MALTITOL (UNII: D65DG142WK)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	Score
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Shape		Size	
Flavor	GRAPE (Grape Flavor)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58657-505-08	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/14/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	06/14/2016	

Labeler - Method Pharmaceuticals (060216698)

Revised: 2/2020

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