

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 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

 <p>METHOD PHARMACEUTICALS</p> <p>NDC 58657-505-08</p> <p>Guaifenesin and Dextromethorphan Hydrobromide Syrup</p> <p>100 mg/10 mg/5 mL</p> <p>Expectorant Cough Suppressant</p> <p>Grape Flavor</p> <p>Non Drowsy • Alcohol Free</p> <p>FOR AGES 12 AND UP</p> <p>8 fl. oz. (237mL)</p>	<p>Drug Facts</p> <p>Active ingredient (in each 5 mL) Purpose</p> <p>Dextromethorphan Hydrobromide 10 mg Cough Suppressant</p> <p>Guaifenesin 100 mg Expectorant</p> <p>Uses</p> <ul style="list-style-type: none"> temporarily relieves cough due to minor throat and bronchial irritation helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive <p>Warnings</p> <p>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.</p> <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> persistent cough or chronic cough such as occurs with smoking, asthma, chronic bronchitis, emphysema cough accompanied by excessive phlegm (mucus) <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> 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 <p>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.</p>	<p>Drug Facts (continued)</p> <p>Directions</p> <ul style="list-style-type: none"> 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 <table border="1"> <tr> <td>adults and children 12 years and over</td> <td>2 teaspoonfuls (TSP) every 4 hours</td> </tr> <tr> <td>children under 12 years</td> <td>DO NOT USE</td> </tr> </table> <p>Inactive ingredients</p> <p>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</p> <p>Other information</p> <ul style="list-style-type: none"> store at room temperature 20°-25°C (68°-77°F) <p>Questions 1-877-250-3427</p> <p>Manufactured For: Method Pharmaceuticals, LLC Fort Worth, TX 76118</p> <p>Rev. 06/2016</p>  <p>N 3 58657-50508 0</p> <p>Lot: _____ Exp.: _____</p>	adults and children 12 years and over	2 teaspoonfuls (TSP) every 4 hours	children under 12 years	DO NOT USE
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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: 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)	
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	
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 Drug	M012	06/14/2016	

Labeler - Method Pharmaceuticals (060216698)

Revised: 12/2023

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