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.

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Guaifenesin and DextromethorphanHydrobromide 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

<table>
<thead>
<tr>
<th>adults and children 12 years and over</th>
<th>2 teaspoonfuls (TSP) every 4 hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>children under 12 years</td>
<td>DO NOT USE</td>
</tr>
</tbody>
</table>

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
GUAIFENESIN AND DEXTROMETHORPHAN HYDROBROMIDE
guaifenesin and dextromethorphan hydrobromide syrup

Product Information

Product Type: HUMAN OTC DRUG  
Route of Administration: ORAL

Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
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<tbody>
<tr>
<td>DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RT9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)</td>
<td>DEXTROMETHORPHAN HYDROBROMIDE</td>
<td>10 mg in 5 mL</td>
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<tr>
<td>GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)</td>
<td>GUAIFENESIN</td>
<td>100 mg in 5 mL</td>
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Inactive Ingredients

<table>
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<tr>
<th>Ingredient Name</th>
<th>Strength</th>
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<tr>
<td>GLYCERIN (UNII: PDC6A3C0OX)</td>
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<tr>
<td>MALTITOL (UNII: D65DG142WK)</td>
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<td>SACCHARIN SODIUM (UNII: SB8ZUX40TY)</td>
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<td>PROPYLENE GLYCOL (UNII: 6DC9Q167V3)</td>
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<tr>
<td>ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)</td>
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<tr>
<td>TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)</td>
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<td>SORBITOL (UNII: 506T60A25R)</td>
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Product Characteristics

Color:  
Score:  

Drug Facts

Active Ingredient (in each 5 mL)  
GUAIFENESIN AND DEXTROMETHORPHAN HYDROBROMIDE 10 mg  
Cough Suppressant

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 have stopped taking a MAOI drug within 2 weeks. 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 a persistent cough or chronic cough such as occurs with smoking, asthma, chronic bronchitis, emphysema
- cough accompanied by excessive phlegm (mucus)
- other medical conditions, allergies
- pregnant or breast-feeding
- allergic to any ingredients

Directions
- Do not exceed 8 doses in any 24-hour period. If symptoms persist for more than 1 week, consult a doctor.
- Children under 12 years of age: Ask a doctor.

Inactive Ingredients
- Citric acid, citric acid, 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°C-25°C (68°F-77°F)

Questions
- 1-877-293-5427

Manufactured For:
Method Pharmaceuticals, LLC
Fort Worth, TX 76116

Rev. 06/2016
<table>
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### Packaging

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<td>06/14/2016</td>
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### Marketing Information

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<td>OTC monograph final</td>
<td>part341</td>
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**Labeler** - Method Pharmaceuticals (060216698)

Revised: 2/2020