GUAIFENESIN DM- guaifenesin and dextromethorphan syrup
Pharmaceutical Associates, Inc.

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 DM
Non-Narcotic, Alcohol Free
Expectorant/Cough Suppressant

DESCRIPTION

Each 5 mL (1 teaspoonful) contains:
Guaifenesin 100 mg
Dextromethorphan 10 mg
Hydrobromide

Inactive Ingredients: Citric acid, FD&C Red No. 40, flavoring, glycerin, menthol, purified water, sodium benzoate, sodium citrate, sodium saccharin, and sucrose.

Sodium Content: 4 mg/5 mL

USES
- helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive
- temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold

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
- 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.
- you are hypersensitive to any of the 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.

Professional Note: Guaifenesin has been shown to produce a color interference with certain clinical laboratory determinations of 5-hydroxyindoleacetic acid (5-HIAA) and vanillylmandelic acid (VMA).
**DIRECTIONS:** Follow dosage below or use as directed by a physician.
- do not take more than 6 doses in any 24-hour period.

<table>
<thead>
<tr>
<th>age</th>
<th>dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>adults and children</td>
<td>10 mL (2 teaspoonfuls) every 4 hours</td>
</tr>
<tr>
<td>12 years and over</td>
<td></td>
</tr>
<tr>
<td>children 6 years to under 12 years</td>
<td>5 mL (1 teaspoonful) every 4 hours</td>
</tr>
<tr>
<td>children 2 years to under 6 years</td>
<td>2.5 mL (1/2 teaspoonful) every 4 hours</td>
</tr>
<tr>
<td>children under 2 years</td>
<td>ask a doctor</td>
</tr>
</tbody>
</table>

**HOW SUPPLIED:** Guaifenesin Syrup and Dextromethorphan is a red, cherry flavored syrup supplied in the following oral dosage forms:

- NDC 0121-0638-04: 4 fl oz (118 mL) bottle
- NDC 0121-0638-08: 8 fl oz (237 mL) bottle
- NDC 0121-0638-16: 16 fl oz (473 mL) bottle
- NDC 0121-0638-05: 5 mL unit dose cup
- NDC 0121-0638-00: Case contains 100 unit dose cups of 5 mL (0121-0638-05) packaged in 10 trays of 10 unit dose cups each.
- NDC 0121-1276-10: 10 mL unit dose cup
- NDC 0121-1276-00: Case contains 100 unit dose cups of 10 mL (0121-1276-10) packaged in 10 trays of 10 unit dose cups each.

**STORAGE:** Keep tightly closed. Store at controlled room temperature, 20°-25°C (68°-77°F) [See USP]. Protect from light.

**MANUFACTURED BY**
Pharmaceutical Associates, Inc.
Greenville, SC 29605
www.paipharma.com
R11/16

**PRINCIPAL DISPLAY PANEL - 5 mL Unit Dose Cup Label**
Delivers 5 mL
NDC 0121-0638-05
GUAIFENESIN SYRUP and DEXTROMETHORPHAN
100 mg/10 mg per 5 mL
FOR INSTITUTIONAL USE ONLY
PHARMACEUTICAL ASSOCIATES, INC.
GREENVILLE, SC 29605
Delivers 10 mL
NDC 0121-1276-10
GUAIFENESIN SYRUP
and DEXTROMETHORPHAN
200 mg/20 mg per 10 mL
FOR INSTITUTIONAL USE ONLY
PHARMACEUTICAL ASSOCIATES, INC.
GREENVILLE, SC 29605
SEE INSERT
A06381001
PRINCIPAL DISPLAY PANEL - 118 mL Bottle Label

NDC 0121-0638-04
NSN 6505-01-318-1565

Quality®
Value

Guaifenesin-DM

100 mg/10 mg per 5 mL

EXPECTORANT/COUGH SUPPRESSANT

Compare to the active ingredients in
*Robitussin®-DM

CONTROLS COUGHS

LOOSENS AND RELIEVES CHEST CONGESTION

4 fl oz (118 mL)

Pharmaceutical Associates, Inc.
Greenville, SC 29605

DRUG FACTS

Active Ingredient (in each 5 mL teaspoonful) Purpose

Guaifenesin 100 mg.................................................Expectorant
Dextromethorphan Hydrobromide 10 mg........Cough Suppressant

Uses
• helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive
• temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold

**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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**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

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<th>age</th>
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<tbody>
<tr>
<td>adults and children 12 years and over</td>
<td>2 teaspoonfuls every 4 hours</td>
</tr>
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<td>1 teaspoonful every 4 hours</td>
</tr>
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<td>1/2 teaspoonful every 4 hours</td>
</tr>
<tr>
<td>under 2 years</td>
<td>ask a doctor</td>
</tr>
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</table>

**Other Information**
• store at 20°-25°C (68°-77°F)
• alcohol-free
• packaged with tamper evident seal around cap
• sodium content 4 mg/5 mL

**Inactive ingredients:** citric acid, FD&C Red No. 40, flavoring, glycerin, menthol, purified water, sodium benzoate, sodium citrate, sodium saccharin, and sucrose.

*Robitussin® is a registered trademark of Wyeth Consumer Healthcare.*
PRINCIPAL DISPLAY PANEL - 237 mL Bottle Label

NDC 0121-0638-08

Quality®
Value

Guaifenesin-DM

100 mg/10 mg per 5 mL

EXpectorant/Cough Suppressant

Compare to the active ingredients in
*Robitussin®-DM

CONTROLS COUGHS
LOOSENS AND RELIEVES CHEST CONGESTION

4 fl oz (118 mL)

Pharmaceutical Associates, Inc.
Greenville, SC 29605

DRUG FACTS

Active Ingredient (in each 5 mL teaspoonful) Purpose

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Dextromethorphan Hydrobromide 10 mg......Cough Suppressant

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<td>1/2 teaspoonful every 4 hours</td>
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<td>under 2 years</td>
<td>ask a doctor</td>
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</tbody>
</table>

**Other Information**
- store at 20°-25°C (68°-77°F)
- alcohol-free
- packaged with tamper evident seal around cap
- sodium content 4 mg/5 mL

**Inactive ingredients:** citric acid, FD&C Red No. 40, flavoring, glycerin, menthol, purified water, sodium benzoate, sodium citrate, sodium saccharin, and sucrose.

*Robitussin®* is a registered trademark of Wyeth Consumer Healthcare.

R11/04
NDC 0121-0638-16

Quality® Value

Guaifenesin-DM

100 mg/10 mg per 5 mL

EXPECTORANT/COUGH SUPPRESSANT

Compare to the active ingredients in *Robitussin®-DM

CONTROLS COUGHS
LOOSENS AND RELIEVES CHEST CONGESTION

16 fl oz (473 mL)

Pharmaceutical Associates, Inc.
Greenville, SC 29605

DRUG FACTS

Active Ingredient (in each 5 mL teaspoonful) Purpose

Guaifenesin 100 mg..........................Expectorant
Dextromethorphan Hydrobromide 10 mg......Cough Suppressant

Uses

• helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive
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<td>12 years and over</td>
<td>every 4 hours</td>
</tr>
<tr>
<td>children 6 years to under 12 years</td>
<td>1 teaspoonful</td>
</tr>
<tr>
<td>under 12 years</td>
<td>every 4 hours</td>
</tr>
<tr>
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<td>1/2 teaspoonful</td>
</tr>
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Other Information
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- alcohol-free
- packaged with tamper evident seal around cap
- sodium content 4 mg/5 mL

Inactive ingredients: citric acid, FD&C Red No. 40, flavoring, glycerin, menthol, purified water, sodium benzoate, sodium citrate, sodium saccharin, and sucrose.

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R08/04
GUAIFENESIN DM
guaiifenesin and dextromethorphan syrup

Product Information

<table>
<thead>
<tr>
<th>Product Type</th>
<th>HUMAN OTC DRUG</th>
<th>Item Code (Source)</th>
<th>NDC:0121-0638</th>
</tr>
</thead>
<tbody>
<tr>
<td>Route of Administration</td>
<td>ORAL</td>
<td></td>
<td></td>
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</table>

Active Ingredient/Active Moiety

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

Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)</td>
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</tr>
<tr>
<td>FD&amp;C RED NO. 40 (UNII: WZB9127X0A)</td>
<td></td>
</tr>
<tr>
<td>GLYCERIN (UNII: PDC6A3C00X)</td>
<td></td>
</tr>
<tr>
<td>MENTHOL (UNII: L7T10EIP3A)</td>
<td></td>
</tr>
<tr>
<td>WATER (UNII: 059QF0KOOR)</td>
<td></td>
</tr>
<tr>
<td>SODIUM BENZOATE (UNII: OJ245FE5EU)</td>
<td></td>
</tr>
<tr>
<td>SODIUM CITRATE (UNII: IQ73Q2JULR)</td>
<td></td>
</tr>
<tr>
<td>SACCHARIN SODIUM (UNII: SB8ZUX40TY)</td>
<td></td>
</tr>
</tbody>
</table>
SUCROSE (UNII: C151H8M554)

### Product Characteristics
<table>
<thead>
<tr>
<th>Color</th>
<th>red</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shape</td>
<td>Score</td>
</tr>
<tr>
<td>Flavor</td>
<td>CHERRY</td>
</tr>
<tr>
<td>Contains</td>
<td></td>
</tr>
</tbody>
</table>

### Packaging
<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>NDC:0121-0638-00</td>
<td>10 in 1 CASE</td>
<td></td>
<td>07/01/1992</td>
</tr>
<tr>
<td>1</td>
<td>NDC:0121-0638-05</td>
<td>10 in 1 TRAY</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>NDC:0121-0638-04</td>
<td>5 mL in 1 CUP; UNIT-DOSE; Type 0: Not a Combination Product</td>
<td></td>
<td>07/01/1992</td>
</tr>
<tr>
<td>2</td>
<td>NDC:0121-0638-04</td>
<td>118 mL in 1 BOTTLE; Type 0: Not a Combination Product</td>
<td></td>
<td>07/01/1992</td>
</tr>
<tr>
<td>3</td>
<td>NDC:0121-0638-08</td>
<td>237 mL in 1 BOTTLE; Type 0: Not a Combination Product</td>
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<td>07/01/1992</td>
</tr>
<tr>
<td>4</td>
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<td>473 mL in 1 BOTTLE; Type 0: Not a Combination Product</td>
<td></td>
<td>07/01/1992</td>
</tr>
</tbody>
</table>

### Marketing Information
<table>
<thead>
<tr>
<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
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<tbody>
<tr>
<td>OTC monograph final</td>
<td>part341</td>
<td>07/01/1992</td>
<td></td>
</tr>
</tbody>
</table>

### GUAIFENESIN DM
guaifenesin and dextromethorphan syrup

### Product Information
<table>
<thead>
<tr>
<th>Product Type</th>
<th>Item Code (Source)</th>
</tr>
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<tbody>
<tr>
<td>HUMAN OTC DRUG</td>
<td>NDC:0121-1276</td>
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<tr>
<td>ORAL</td>
<td></td>
</tr>
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### Active Ingredient/Active Moiety
<table>
<thead>
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<th>Ingredient Name</th>
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<td>10 mg in 5 mL</td>
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### Inactive Ingredients
<table>
<thead>
<tr>
<th>Ingredient Name</th>
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</tr>
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<tbody>
<tr>
<td></td>
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</table>
SODIUM BENZOATE (UNII: OJ245FE5EU)
SODIUM CITRATE (UNII: 1Q73Q2JULR)
SACCHARIN SODIUM (UNII: SB8ZUX40TY)
SUCROSE (UNII: C151H8M554)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)
FD&C RED NO. 40 (UNII: WZB9127XOA)
GLYCERIN (UNII: PDC6A3C0OX)
MENTHOL (UNII: L7T10EIP3A)
WATER (UNII: 059QF0KO0R)

Product Characteristics

<table>
<thead>
<tr>
<th>Color</th>
<th>red</th>
<th>Score</th>
<th>Shape</th>
<th>Size</th>
<th>Flavor</th>
<th>Imprint Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contains</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>CHERRY</td>
<td></td>
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Packaging

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<td></td>
<td>10 in 1 TRAY</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>NDC:0121-1276-10</td>
<td>10 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product</td>
<td></td>
<td></td>
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Labeler - Pharmaceutical Associates, Inc. (044940096)

Establishment

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>ID/FEI</th>
<th>Business Operations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmaceutical Associates, Inc.</td>
<td></td>
<td>097630693</td>
<td>manufacture(0121-0638, 0121-1276)</td>
</tr>
</tbody>
</table>

Revised: 3/2017