

GUAIFENESIN DM- guaifenesin and dextromethorphan syrup
PAI Holdings, LLC dba PAI Pharma

GUAIFENESIN DM

Non-Narcotic, Alcohol Free
Expectorant/Cough Suppressant

DESCRIPTION

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

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.

age	dose
adults and children 12 years and over	10 mL (2 teaspoonfuls) every 4 hours
children 6 years to under 12 years	5 mL (1 teaspoonful) every 4 hours
children 2 years to under 6 years	2.5 mL (1/2 teaspoonful) every 4 hours
children under 2 years	ask a doctor

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 01210638-05: 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

Package Not Child-Resistant

PHARMACEUTICAL ASSOCIATES, INC.
GREENVILLE, SC 29605

SEE INSERT



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

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)

pai Pharmaceutical
Associates, Inc.
Greenville, SC 29605

Drug Facts

Active Ingredients (in each 5 mL teaspoonful)

Guaifenesin 100 mg	Expectorant
Dextromethorphan Hydrobromide 10 mg	Cough suppressant

Purpose

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.

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. ▶

Drug Facts (continued)

Directions ■ do not take more than 6 doses in any 24-hour period

age	dose
adults and children 12 years and over	2 teaspoonfuls every 4 hours
children 6 years to under 12 years	1 teaspoonful every 4 hours
children 2 years to under 6 years	1/2 teaspoonful every 4 hours
under 2 years	ask a doctor

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.

N
3 0121-0638-04 6

LOT:
EXP:

R11/06

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

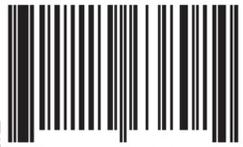
**LOOSENS AND RELIEVES
CHEST CONGESTION**

8 fl oz (237 mL)

**Pharmaceutical
Associates, Inc.
Greenville, SC 29605**

<p>Drug Facts</p> <p>Active ingredients (in each 5 mL teaspoonful) Purpose Guaifenesin 100 mg.....Expectorant Dextromethorphan Hydrobromide 10 mg.....Cough Suppressant</p> <p>Uses</p> <ul style="list-style-type: none">■ 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 <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">■ cough that occurs with too much phlegm (mucus)■ cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis, or emphysema <p>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.</p> <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><small>*Robitussin® is a registered trademark of Wyeth Consumer Healthcare.</small></p>	<p>NDC 0121-0638-08</p> <p>Quality® Value</p> <p>Guaifenesin-DM</p> <p>100 mg/10 mg per 5 mL</p> <p>EXPECTORANT / COUGH SUPPRESSANT</p> <p>Compare to the active ingredients in *Robitussin®-DM</p> <p>CONTROLS COUGHS LOOSENS AND RELIEVES CHEST CONGESTION</p> <p>8 fl oz (237 mL)</p> <p>pai Pharmaceutical Associates, Inc. Greenville, SC 29605</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 <table border="1"><thead><tr><th>age</th><th>dose</th></tr></thead><tbody><tr><td>adults and children 12 years and over</td><td>2 teaspoonfuls every 4 hours</td></tr><tr><td>children 6 years to under 12 years</td><td>1 teaspoonful every 4 hours</td></tr><tr><td>children 2 years to under 6 years</td><td>1/2 teaspoonful every 4 hours</td></tr><tr><td>under 2 years</td><td>ask a doctor</td></tr></tbody></table> <p>Other Information</p> <ul style="list-style-type: none">■ store at 20°-25°C (68°-77°F) ■ alcohol-free■ packaged with tamper evident seal around cap■ sodium content 4 mg/5 mL <p>Inactive ingredients: citric acid, FD&C Red No.40, flavoring, glycerin, menthol, purified water, sodium benzoate, sodium citrate, sodium saccharin, and sucrose.</p>	age	dose	adults and children 12 years and over	2 teaspoonfuls every 4 hours	children 6 years to under 12 years	1 teaspoonful every 4 hours	children 2 years to under 6 years	1/2 teaspoonful every 4 hours	under 2 years	ask a doctor
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children 2 years to under 6 years	1/2 teaspoonful every 4 hours											
under 2 years	ask a doctor											

R11/04

3  4

0121-0638-08

LOT: EXP:

PRINCIPAL DISPLAY PANEL - 473 mL Bottle Label

NDC 0121-0638-16

**Quality®
Value**

Guaifenesin-DM

100 mg/10 mg per 5 mL

EXPECTORANT/COUGH SUPPRESSANT

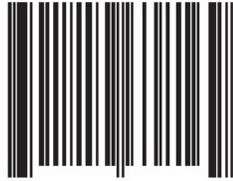
**Compare to the
active ingredients in
*Robitussin®-DM**

CONTROLS COUGHS

**LOOSENS AND RELIEVES
CHEST CONGESTION**

16 fl oz (473 mL)

**Pharmaceutical
Associates, Inc.**
Greenville, SC 29605

<p>Drug Facts</p> <p>Active ingredients (in each 5 mL teaspoonful) Purpose Guaifenesin 100 mg.....Expectorant Dextromethorphan Hydrobromide 10 mg.....Cough Suppressant</p> <p>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</p> <p>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</p> <p>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.</p> <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><small>*Robitussin® is a registered trademark of Wyeth Consumer Healthcare.</small></p> <p>LOT: EXP.</p>	<p>NDC 0121-0638-16</p> <p>Quality Value®</p> <p>Guaifenesin-DM</p> <p>100 mg/10 mg per 5 mL</p> <p>EXPECTORANT / COUGH SUPPRESSANT</p> <p>Compare to the active ingredients in *Robitussin®-DM</p> <p>CONTROLS COUGHS</p> <p>LOOSENS AND RELIEVES CHEST CONGESTION</p> <p>16 fl oz (473 mL)</p> <p>pai Pharmaceutical Associates, Inc. Greenville, SC 29605</p>	<p>Drug Facts (continued)</p> <p>Directions ■ do not take more than 6 doses in any 24-hour period</p> <table border="1"> <thead> <tr> <th>age</th> <th>dose</th> </tr> </thead> <tbody> <tr> <td>adults and children 12 years and over</td> <td>2 teaspoonfuls every 4 hours</td> </tr> <tr> <td>children 6 years to under 12 years</td> <td>1 teaspoonful every 4 hours</td> </tr> <tr> <td>children 2 years to under 6 years</td> <td>1/2 teaspoonful every 4 hours</td> </tr> <tr> <td>under 2 years</td> <td>ask a doctor</td> </tr> </tbody> </table> <p>Other Information ■ store at 20°-25°C (68°-77°F) ■ alcohol-free ■ packaged with tamper evident seal around cap ■ sodium content 4 mg/5mL</p> <p>Inactive ingredients: citric acid, FD&C Red No.40, flavoring, glycerin, menthol, purified water, sodium benzoate, sodium citrate, sodium saccharin, and sucrose.</p> <p style="text-align: right;">R08/04</p> <div style="text-align: center;">  <p>3 0121-0638-16 9</p> </div>	age	dose	adults and children 12 years and over	2 teaspoonfuls every 4 hours	children 6 years to under 12 years	1 teaspoonful every 4 hours	children 2 years to under 6 years	1/2 teaspoonful every 4 hours	under 2 years	ask a doctor
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under 2 years	ask a doctor											

PRINCIPAL DISPLAY PANEL - 10 mL Unit Dose Cup Label

Delivers 10 mL

NDC 0121-1276-10

GUAIFENESIN SYRUP

and DEXTROMETHORPHAN

200 mg/20 mg per 10 mL

Package Not Child-Resistant

PHARMACEUTICAL ASSOCIATES, INC.

GREENVILLE, SC 29605

SEE INSERT



GUAIFENESIN DM

guaifenesin and dextromethorphan syrup

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0121-0638
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	

MENTHOL (UNII: L7T10EIP3A)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SUCROSE (UNII: C151H8M554)	

Product Characteristics

Color	red	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0121-0638-00	10 in 1 CASE	07/01/1992	
1		10 in 1 TRAY		
1	NDC:0121-0638-05	5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
2	NDC:0121-0638-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/1992	
3	NDC:0121-0638-08	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/1992	
4	NDC:0121-0638-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/1992	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	07/01/1992	

GUAIFENESIN DM

guaifenesin and dextromethorphan syrup

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0121-1276
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 10 mL

DEXTROMETHORPHAN (UNII: 7355X3ROTS) (DEXTROMETHORPHAN - UNII:7355X3ROTS)

DEXTROMETHORPHAN
HYDROBROMIDE

20 mg
in 10 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SUCROSE (UNII: C151H8M554)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
MENTHOL (UNII: L7T10EIP3A)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	red	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0121-1276-00	10 in 1 CASE	07/01/1992	
1		10 in 1 TRAY		
1	NDC:0121-1276-10	10 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	07/01/1992	

Labeler - PAI Holdings, LLC dba PAI Pharma (044940096)

Registrant - PAI Holdings, LLC (044940096)

Establishment

Name	Address	ID/FEI	Business Operations
PAI Holdings, LLC dba Pharmaceutical Associates, Inc. and dba PAI Pharma		097630693	manufacture(0121-0638, 0121-1276)

