GUAIFENESIN DM- guaifenesin and dextromethorphan syrup
PAI Holdings, LLC

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

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

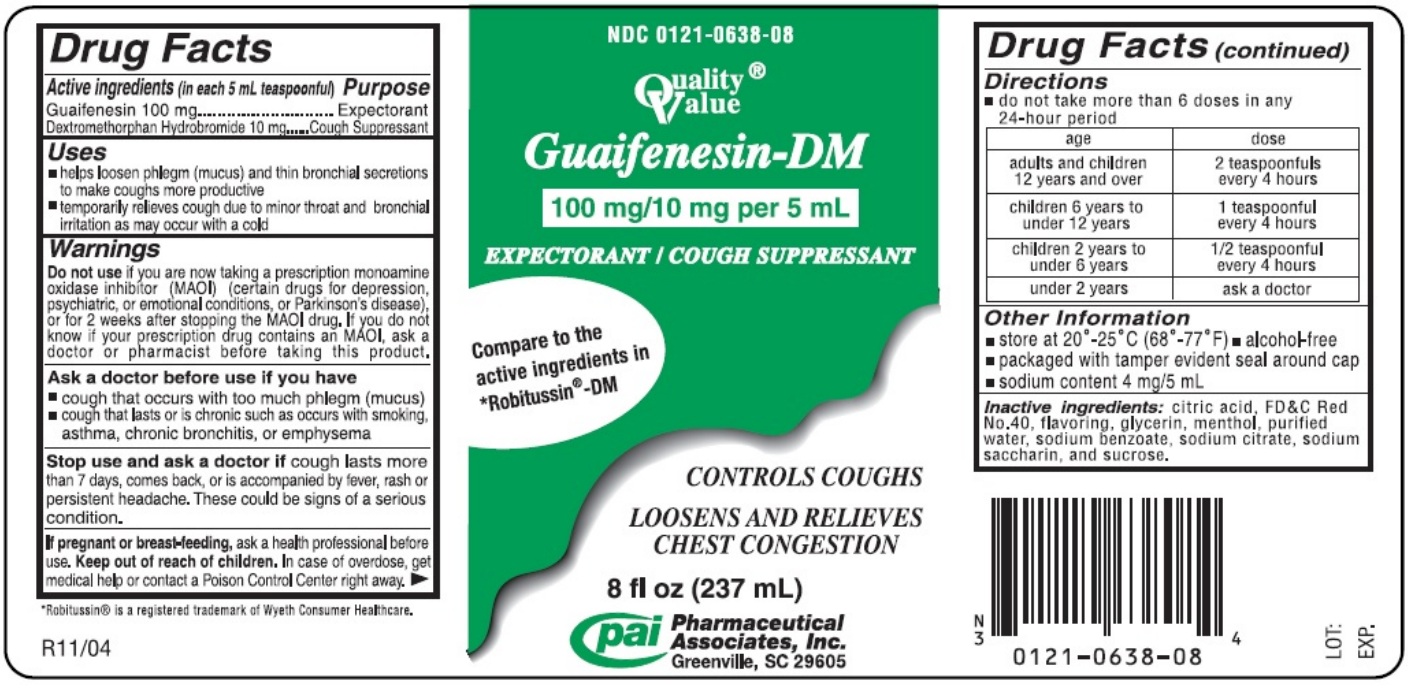
***Robitussin ®-DM**

CONTROLS COUGHS

LOOSENS AND RELIEVES CHEST CONGESTION

8 fl oz (237 mL)

Pharmaceutical Associates, Inc.
Greenville, SC 29605



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

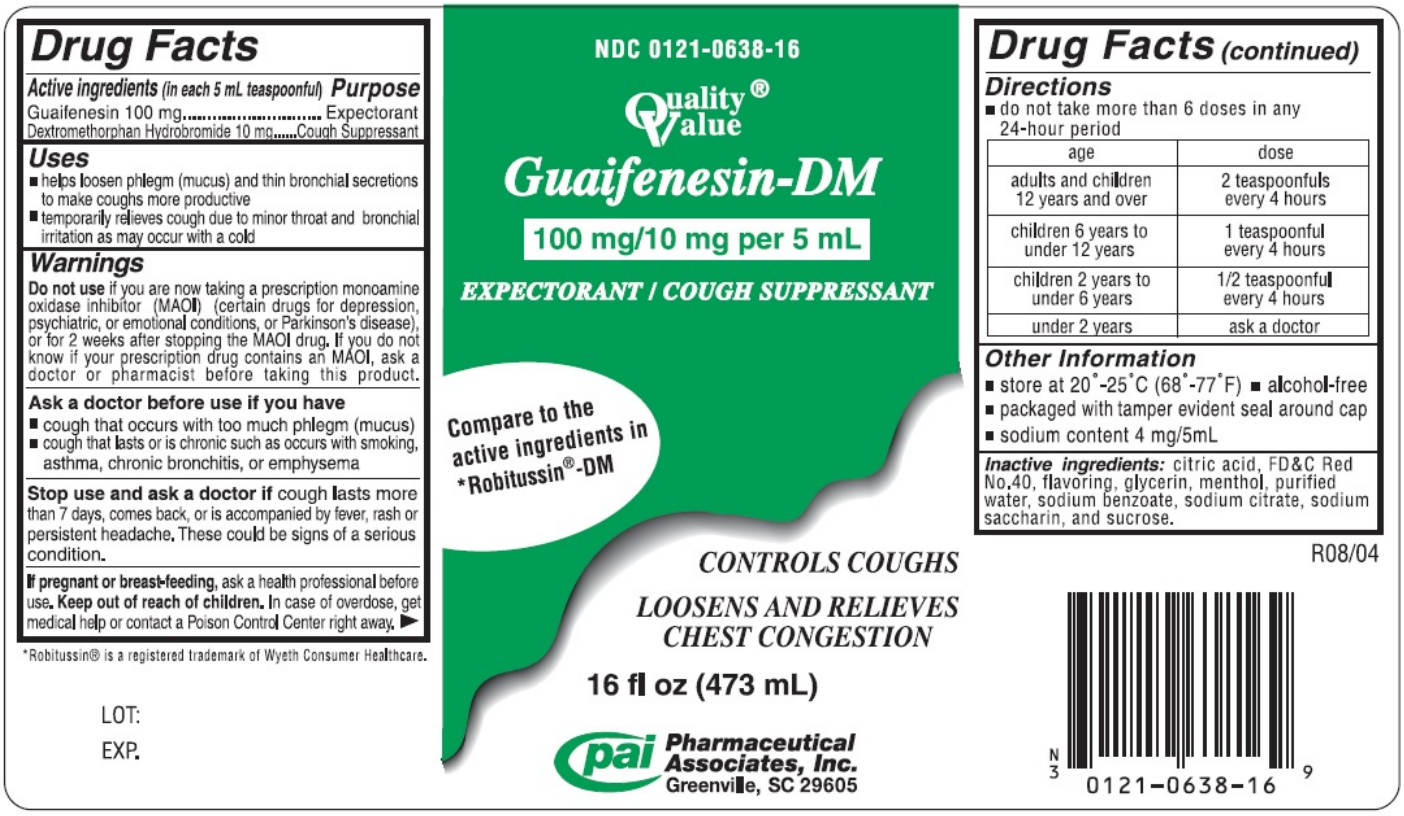
**Compare to the
active ingredients in
*Robitussin ®-DM**

CONTROLS COUGHS

**LOOSENS AND RELIEVES
CHEST CONGESTION**

16 fl oz (473 mL)

Pharmaceutical Associates, Inc.
Greenville, SC 29605



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 (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)