

**DEXTROMETHORPHAN HBR. AND GUAIFENESIN- dextromethorphan hbr. and guaifenesin solution**  
**Rising Pharma Holdings, Inc.**

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***DRUG FACTS***

**10 mg-100 mg/5 mL -**

***Active ingredient per 5 mL (1 unit dose)***

Dextromethorphan HBr. 10 mg

Guaifenesin 100 mg

**20 mg-200 mg/10 mL -**

***Active ingredient per 10 mL (1 unit dose)***

Dextromethorphan HBr. 20 mg

Guaifenesin 200 mg

***Purpose***

Cough Suppressant

Expectorant

***Uses***

- temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold
- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes

***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 healthcare professional before use.**

**Keep out of reach of children.** In case of accidental overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

### Directions

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

### 20 mg-200 mg/10 mL

age	dose
Children under 12 years of age	Do not use
Adults and children over 12 years of age	10 mL (1 unit dose) every 4 hours

### 10 mg-100 mg/5 mL

age	dose
Children under 6 years of age	Do not use
Children 6 to under 12 years of age	5 mL (1 unit dose) every 4 hours
Adults and children over 12 years of age	10 mL (2 unit dose) every 4 hours

### Other Information

- store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature]
- do not use if lid is torn or broken

**Inactive Ingredients** citric acid, FD&C red#40, flavor, menthol, methylparaben, propylene glycol, propylparaben, purified water, sodium citrate, and sucralose.

### NDC Information -

**Each 5 mL** of Guaifenesin Syrup and Dextromethorphan contains Guaifenesin 100mg and Dextromethorphan Hydrobromide 10mg and is supplied in the following oral dosage forms:

**NDC 57237-312-05 unit dose cup 5mL**

**NDC 57237-312-51 (100 x 5 mL) unit-dose cups**

**Each 10 mL** of Guaifenesin Syrup and Dextromethorphan contains Guaifenesin 200mg and Dextromethorphan Hydrobromide 20mg and is supplied in the following oral dosage forms:

**NDC 57237-313-01 unit dose cup 10mL**

**NDC 57237-313-18 (80 x 10 mL) unit-dose cups**

**Questions or comments?** Call 1-844-474-7464

**Distributed by:**

Rising Pharma Holdings, Inc.

East Brunswick, NJ 08816

**Issued:** 04/2023

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

**10 mg-100 mg/5 mL**

**Lid Label      NDC 57237-312-05**

Delivers 5 mL  
**Dextromethorphan HBr**  
**Guaifenesin**  
**Oral Solution**

10 mg-100 mg / 5 mL

FOR INSTITUTIONAL USE ONLY

Exp: **yyyy/mm** Lot#: **XXXXXX**

Dist. By: Rising Pharma Holdings, Inc.

East Brunswick, NJ 08816

Iss. 05/2023

FG-28

See Label



5723731205

L4



Case Label NDC 57237-312-51

**Dextromethorphan HBr. and Guaifenesin Oral Solution**  
**10 mg-100 mg/5 mL**

**Cough Suppressant/Expectorant**

- Alcohol Free
- Sugar Free
- Cherry Flavor

**USUAL DOSAGE:** See attached Drug Facts

FOR INSTITUTIONAL USE ONLY

100 x 5 mL Unit-Dose Cups

**Drug Facts**

**Active ingredient per 5 mL (1 unit dose)**

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

**Uses**

- temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold
- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes

**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 healthcare professional before use.

Keep out of reach of children. In case of accidental overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222)

**Directions**

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

age	dose
Children under 6 years of age	Do not use
Children 6 to under 12 years of age	5 mL (1 unit dose) every 4 hours
Adults and children over 12 years of age	10 mL (2 unit dose) every 4 hours

**Other information**

- store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature]
- do not use if lid is torn or broken

**Inactive ingredients:** citric acid, FD&C red#40, flavor, menthol, methylparaben, propylene glycol, propylparaben, purified water, sodium citrate, and sucralose.

Questions or comments? Call 1-844-474-7464

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Rising Pharma Holdings, Inc.  
 East Brunswick, NJ 08816

FG-28/Rev.: 04/2023



NDC 57237-312-51

**Dextromethorphan HBr. and Guaifenesin Oral Solution**

**10 mg-100 mg/5 mL**

100 x 5 mL Unit-Dose Cups



LOT#

Exp. Date:

Unvarnished Area

**20 mg-200 mg/10 mL**

**Lid Label NDC 57237-313-01**

Delivers 10 mL  
**Dextromethorphan HBr**  
**Guaifenesin**  
**Oral Solution**

20 mg-200 mg /10 mL

FOR INSTITUTIONAL USE ONLY

Exp: yyyy/mm      Lot#: XXXXXX

Dist. By: Rising Pharma Holdings, Inc.

East Brunswick, NJ 08816

Iss. 05/2023

FG-29

See Label



5723731301

L4



Case Label    NDC 57237-313-18

**Rising** NDC 57237-313-18

**Dextromethorphan HBr. and Guaifenesin Oral Solution**  
20 mg-200 mg/10 mL

**Cough Suppressant/Expectorant**

- Alcohol Free
- Sugar Free
- Cherry Flavor

**USUAL DOSAGE:** See attached Drug Facts

FOR INSTITUTIONAL USE ONLY

80 x 10 mL Unit-Dose Cups

<b>Drug Facts</b>	
<b>Active ingredient per 10 mL (1 unit dose)</b> Dextromethorphan HBr. 20 mg. Guaifenesin 200 mg.	<b>Purpose</b> Cough Suppressant Expectorant
<b>Uses</b>	temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes
<b>Warnings</b>	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. <b>Ask a doctor before use if you have</b> • cough that occurs with too much phlegm (mucus) • cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis, or emphysema
<b>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.</b>	
<b>If pregnant or breast-feeding, ask a healthcare professional before use.</b>	
<b>Keep out of reach of children. In case of accidental overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)</b>	
<b>Directions</b>	do not take more than 6 doses in any 24 hour period
<b>age</b>	<b>dose</b>
Children under 12 years of age	Do not use
Adults and children over 12 years of age	10 mL (1 unit dose) every 4 hours
<b>Other information</b>	
• store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature]	
• do not use if lid is torn or broken	
<b>Inactive ingredients</b> citric acid, FD&C red #40, flavor, menthol, methylparaben, propylene glycol, propylparaben, purified water, sodium citrate, and sucralose.	
<b>Questions or comments?</b> Call 1-844-474-7464	
<b>Distributed by:</b> Rising Pharma Holdings, Inc. East Brunswick, NJ 08816 FG-29/fes.: 04/2023	 N 3 57237 31318 3

NDC 57237-313-18



**Dextromethorphan HBr. and Guaifenesin Oral Solution**  
20 mg-200 mg/10 mL

80 x 10 mL Unit-Dose Cups



LOT#

Exp. Date:

Unvarnished Area

**DEXTROMETHORPHAN HBR. AND GUAIFENESIN**

dextromethorphan hbr. and guaifenesin solution

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:57237-312
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 5 mL
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>FD&amp;C RED NO. 4</b> (UNII: X3W0AM1JLX)	

<b>MENTHOL</b> (UNII: L7T10EIP3A)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	

### Product Characteristics

<b>Color</b>	red	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	CHERRY	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57237-312-51	100 in 1 BOX, UNIT-DOSE	06/12/2023	
1	NDC:57237-312-05	5 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	M012.85	06/12/2023	

## DEXTROMETHORPHAN HBR. AND GUAIFENESIN

dextromethorphan hbr. and guaifenesin solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:57237-313
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 10 mL
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 10 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>FD&amp;C RED NO. 4</b> (UNII: X3W0AM1JLX)	
<b>MENTHOL</b> (UNII: L7T10EIP3A)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	

### Product Characteristics

<b>Color</b>	red	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	CHERRY	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57237-313-18	80 in 1 BOX, UNIT-DOSE	06/12/2023	
1	NDC:57237-313-01	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	M012.85	06/12/2023	

**Labeler** - Rising Pharma Holdings, Inc. (116880195)

Revised: 7/2025

Rising Pharma Holdings, Inc.