

DEXTROMETHORPHAN HBR. AND GUAIFENESIN- dextromethorphan hbr. and guaifenesin solution

Rising Pharma Holdings, 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.

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

Rising 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

Drug Facts							
Active ingredient per 10 mL (1 unit dose) Dextromethorphan HBr. 20 mg. Guaifenesin 200 mg.	Purpose Cough Suppressant Expectorant						
Uses	<ul style="list-style-type: none"> 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	<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 healthcare professional before use.</p> <p>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)</p>						
Directions	<ul style="list-style-type: none"> do not take more than 6 doses in any 24 hour period <table border="1"> <tr> <td>age</td> <td>dose</td> </tr> <tr> <td>Children under 12 years of age</td> <td>Do not use</td> </tr> <tr> <td>Adults and children over 12 years of age</td> <td>10 mL (1 unit dose) every 4 hours</td> </tr> </table>	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
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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						
Other information	<ul style="list-style-type: none"> store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature] do not use if lid is torn or broken <p>Inactive ingredients citric acid, FD&C red #40, flavor, menthol, methylparaben, propylene glycol, propylparaben, purified water, sodium citrate, and sucralose.</p> <p>Questions or comments? Call 1-844-474-7464</p>						
<p>Distributed by: Rising Pharma Holdings, Inc. East Brunswick, NJ 08816 FG-29/fes.: 04/2023</p>							

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

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

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C RED NO. 4 (UNII: X3W0AM1JLX)	

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

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: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 final	part341	06/12/2023	

DEXTROMETHORPHAN HBR. AND GUAIFENESIN

dextromethorphan hbr. and guaifenesin solution

Product Information

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

Active Ingredient/Active Moiety

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

Inactive Ingredients

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

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: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 final	part341	06/12/2023	

Labeler - Rising Pharma Holdings, Inc. (116880195)

Revised: 8/2023

Rising Pharma Holdings, Inc.