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 persistant 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	10 mL (1 unit dose) every 4
years of age	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.

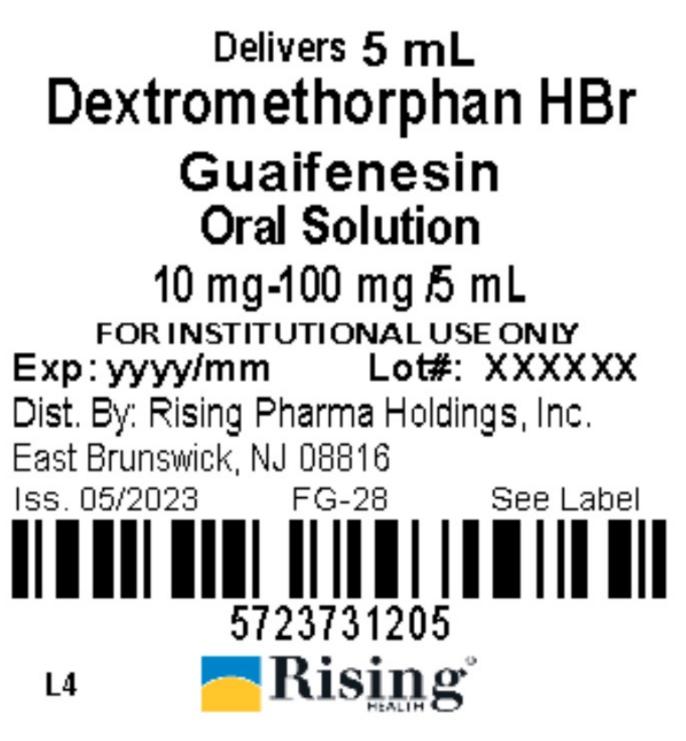
East Brunswick, NJ 08816

Issued: 04/2023

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

10 mg-100 mg/5 mL

Lid Label NDC 57237-312-05

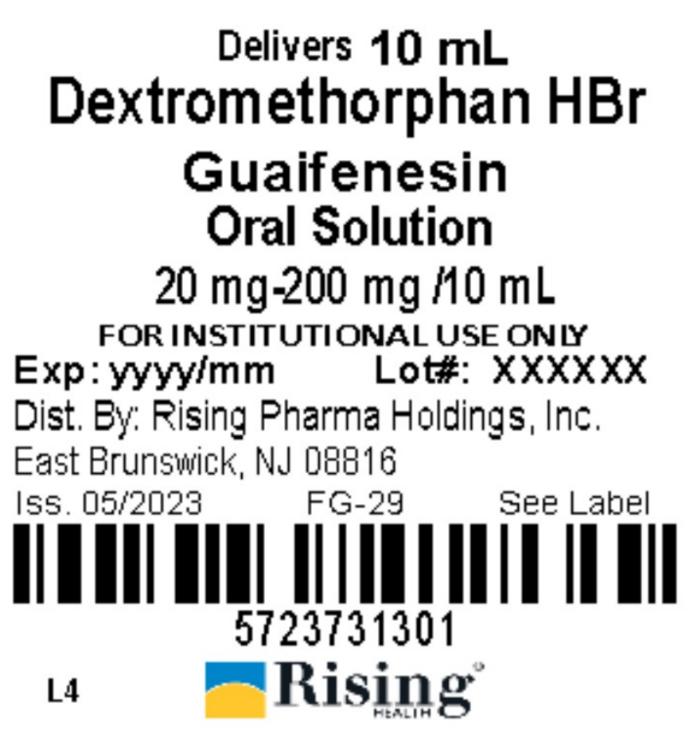


Case Label NDC 57237-312-51

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	Incet and bronchial in nchial secretions to di nchial secretions to di conditions, or Parkins will your prescription with smoking, as conferential overdoas, g contest are professional be contrated overdoas, g contrated overdoas, g contrated overdoas, g contrated overdoas, g	s of age 5 mL (1 unit dose) every 4 hours years of age 10 mL (2 unit dose) every 4 hours to 77°F). [See USP Controlled Room Temperature] broken acid, FD&C red#40, flavor, menthol, methylparaben, propylene acid, FD&C red#40, flavor, menthol, methylparaben, propylene d water, sodium citrate, and sucratose. Call 1-844-474-7454 3 57237 31251 3
Drug Facts FOR INSTITUTIONAL USE ONLY 100 x 5 mL Unit-Dose Cups	Drug Facts Active ingredent per 5 mL (1 unit doe) Active ingredent per 5 mL (1 unit doe) Destromentorphan HB: 10 mg. Destromentorphan HB: 10 mg. Uses • Emporarily relieves cough due to minor throat and old Uses • The pips loosen philogm (mucus) and thin bronchial second drugs for depression, psychiatric, or emotional conditions drugs for depression, psychiatric, or emotional conditions drugs for depression, psychiatric, or emotional conditions drugs for depression, psychiatric, and thin bronchial second the solid state adoctor before use if you have Warrings Warrings Warrings Warrings Out or use if you are now taking a prescription monod drugs for depression, psychiatric, or emotional conditions drugs for depression, psychiatric, are emotional conditions afree adoctor before use if you have Warrings Warrings Warrings Warrings Out or or paresident headaction. These could be significant or the social to the form or toping if pregnant or breast-feeding, aak a heatthcare profe Present and of four or breast-feeding, aak a heatthcare profe Present could be significant under 6 years of age On out take more than 6 doese in any 24 hour period On out take more than 6 doese in any 24 hour period	Children 6 to under 12 years of age Adults and children over 12 years of age entry in formation entry in the set 20° to 25°C (68° to 77°F). [Set of not use if lid is torn of broken Inactive Ingredfents citric actid, FD&C glycol, propylparaben, purified water, sod Questions or comments? Call 1-844-47 Distributed by: FG-28Ass.: 04/2023 FG-28Ass.: 04/2023
NDC 57237-312-51 Do		LOT# Date:

20 mg-200 mg/10 mL

Lid Label NDC 57237-313-01



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 	Drag Part of matching and matching and part of matching and pa
NDC 57237-313-18 D	extromethorphan HBr. and Guaifenesin Oral Solution 20 mg-200 mg/10 mL 80 x 10 mL Unit-Dose Cups

DEXTROMETHORPHAN HBR. AND GUAIFENESIN

dextromethorphan hbr. and guaifenesin solution

Product Information						
Product Type	HUMAN OTC DRUG	Item Code (S	Source)	NDC:57237-312		
Route of Administration	ORAL					
Active Ingredient/Active	Mojety					
	-					
Ingred	lient Name		Basis of Strength		Strength	
		DEXTROMETHORPHAN HYDROBROMIDE		10 mg in 5 mL		
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)		GUAIFENES IN		100 mg in 5 mL		
Inactivo Ingradiante						
Inactive Ingredients						
Ingredient Name				Stre	ength	
ANHYDROUS CITRIC ACID (UNII: >	(F417D3PSL)					
FD&C RED NO. 4 (UNII: X3W0AM1)	LX)					

MENTHOL (UNII: L		• •			
	.7T10EIP3A)				
METHYLPARABEN	(UNII: A2I8C7H	II9T)			
PROPYLENE GLYC	COL (UNII: 6DC9	9Q167V3)			
PROPYLPARABEN	I (UNII: Z8IX2SC	10H)			
WATER (UNII: 0590	QF0KO0R)				
SODIUM CITRATE	(UNII: 1Q73Q2)	JULR)			
SUCRALOSE (UNII	: 96K6UQ3ZD4)				
Product Char	acteristics				
Color		red	Score		
Shape			Size		
Flavor		CHERRY	Imprint C	ode	
Contains					
Packaging					
	P	ackage Description		Marketing Start Date	Marketing End Date
# Item Code	P 100 in 1 BOX,			-	-
 # Item Code 1 NDC:57237- 312-51 NDC:57237 	100 in 1 BOX,	UNIT-DOSE UNIT-DOSE; Type 0: Not		Date	
 # Item Code 1 NDC:57237- 312-51 1 NDC:57237- 	100 in 1 BOX, 5 mL in 1 CUP,	UNIT-DOSE UNIT-DOSE; Type 0: Not		Date	_
 # Item Code 1 NDC:57237- 312-51 1 NDC:57237- 	100 in 1 BOX, 5 mL in 1 CUP,	UNIT-DOSE UNIT-DOSE; Type 0: Not		Date	_
 # Item Code 1 NDC:57237- 312-51 1 NDC:57237- 312-05 	100 in 1 BOX, 5 mL in 1 CUP, Combination P	UNIT-DOSE , UNIT-DOSE; Type 0: Not roduct		Date	_
 NDC:57237- 312-51 NDC:57237- 	100 in 1 BOX, 5 mL in 1 CUP, Combination P	UNIT-DOSE , UNIT-DOSE; Type 0: Not roduct	a	Date	
 # Item Code 1 NDC:57237- 312-51 1 NDC:57237- 312-05 Marketing Marketing 	100 in 1 BOX, 5 mL in 1 CUP, Combination P Informat Applica	UNIT-DOSE , UNIT-DOSE; Type 0: Not roduct tion	a	Date 06/12/2023 Marketing Start	Date Marketing End

DEXTROMETHORPHAN HBR. AND GUAIFENESIN

dextromethorphan hbr. and guaifenesin solution

Product Information						
Product Type	HUMAN OTC DRUG	Item Code (Source) NDC		NDC:572	0:57237-313	
Route of Administration	ORAL					
Active Ingredient/Active Moiety						
Active myreulent/Active	Molety					
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)			GUAIFENES IN		200 mg in 10 mL	
Inactive Ingredients						

Ingredient Name					Strength
ANHYDROUS CIT					
FD&C RED NO. 4	(UNII: X3W0AM1	LJLX)			
MENTHOL (UNII: L	.7T10EIP3A)				
METHYLPARABEN	(UNII: A218C7F	1I9T)			
PROPYLENE GLY	COL (UNII: 6DC	9Q167V3)			
PROPYLPARABEN	I (UNII: Z8IX2SC	C10H)			
WATER (UNII: 059	QF0KO0R)				
SODIUM CITRATE	UNII: 1Q73Q2	JULR)			
SUCRALOSE (UNII	: 96K6UQ3ZD4)				
Product Char	acteristics				
Color		red	Score		
Shape			Size		
Flavor		CHERRY	Imprint C	ode	
Contains					
Packaging					
# Item Code	P	ackage Description		Marketing Start Date	Marketing End Date
1 NDC:57237- 313-18	7- 80 in 1 BOX, UNIT-DOSE			06/12/2023	
1 NDC:57237- 313-0110 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product					
Marketing	Information	tion			
Marketing Category	Applica	ation Number or Mon Citation	ograph	Marketing Start Date	Marketing End Date
OTC monograph fi	nal part341			06/12/2023	

Labeler - Rising Pharma Holdings, Inc. (116880195)

Revised: 8/2023

Rising Pharma Holdings, Inc.