

DEXTROMETHORPHAN HBR AND GUAIFENESIN ORAL SOLUTION-
dextromethorphan hbr and guaifenesin oral solution liquid
KESIN PHARMA CORPORATION

Dextromethorphan HBr and Guaifenesin Oral Solution

Dextromethorphan HBr and Guaifenesin Oral Solution 5 and 10 mL

Disclaimer: Most OTC drugs are not reviewed and approved by the FDA, however, they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

DM Guaifenesin
Non-Narcotic, Sugar, Dye and Alcohol Free
Cough Suppressant/Expectorant

DESCRIPTION

Each 5 mL (1 teaspoonful) contains:
Dextromethorphan Hydrobromide 10 mg
Guaifenesin 100 mg
Each 10 mL (2 teaspoonfuls) contains:
Dextromethorphan Hydrobromide 20 mg
Guaifenesin 200 mg

Inactive Ingredients

Inactive Ingredients: citric acid, glycerin, mixed berry flavor, propylene glycol, purified water, sodium benzoate, sodium saccharin, sorbitol, sucralose, trisodium citrate, xanthan gum
Sodium Content: 4 mg/5 mL

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 make coughs more productive

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

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

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

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

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Follow dosage table 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	10mL (2 teaspoonful) every 4 hours
children 6 to under 12 years of age	5mL (1 teaspoonful) every 4 hours
children 2 to under 6 years of age	2.5mL (1/2 teaspoonful) every 4 hours
children under 2 years	consult a doctor

HOW SUPPLIED

Dextromethorphan hydrobromide and Guaifenesin is a clear, mixed berry flavor solution supplied in the following oral dosage forms:

5 mL unit dose cup:

NDC 81033-103-05

Case containing 100 units dose cups of 5 mL:

NDC 81033-103-50

10 mL unit dose cups:

NDC 81033-103-10

Case containing 100 unit dose cups of 10 mL:

NDC 81033-103-51

STORAGE

Store at controlled temperature 15°C to 30°C (59°F to 86°F) [See USP]. Protect from light.

QUESTIONS OR COMMENTS

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Call 1-833-537-4679

Packaged by:

Kesin Pharma

Oldsmar, FL 34677

Effective 10/2024

Revision 03



PRINCIPAL DISPLAY PANEL - 5 mL Unit Dose Cup Label

NDC 81033-103-05

Dextromethorphan HBr and Guaifenesin Oral Solution

Delivers 10mg/100mg per 5mL

FOR INSTITUTIONAL USE ONLY

Store at 59°F to 86°F (15°C to 30°C)

Delivers 5mL

NDC 81033-103-05

**Dextromethorphan HBr &
Guaifenesin Oral Solution**

10mg/100mg per 5mL

Cough Suppressant
/ Expectorant

Sugar, Alcohol, Dye Free



(01)00381033103051

Store at 68°F to 77°F

See Insert

For Institutional Use Only

Pkg by:

Kesin Pharma
Oldsmar, FL 34677
K2410213
04/30/2026

PRINCIPAL DISPLAY PANEL - 10 mL Unit Dose Cup Label

NDC 81033-103-10

Dextromethorphan HBr and Guaifenesin Oral Solution

Delivers 20mg/200mg per 10mL

FOR INSTITUTIONAL USE ONLY

Store at 59°F to 86°F (15°C to 30°C)

Delivers 10mL

NDC 81033-103-10

**Dextromethorphan HBr &
Guaifenesin Oral Solution**

20mg/200mg per 10mL

Cough Suppressant
/ Expectorant

Sugar, Alcohol, Dye Free



(01)00381033103105

Store at 68°F to 77°F

See Insert

For Institutional Use Only

Pkg by:

Kesin Pharma
Oldsmar, FL 34677
K2410214 04/30/2026



DEXTROMETHORPHAN HBR AND GUAIFENESIN ORAL SOLUTION

dextromethorphan hbr and guaifenesin oral solution liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81033-103(NDC:84447-102)
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 HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
SORBITOL (UNII: 506T60A25R)	
POTASSIUM CITRATE (UNII: EE90ONI6FF)	
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81033-103-50	100 in 1 CASE	12/02/2024	
1	NDC:81033-103-05	5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
2	NDC:81033-103-51	100 in 1 CASE	12/02/2024	
2	NDC:81033-103-10	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	12/02/2024	

Labeler - KESIN PHARMA CORPORATION (117447816)

Establishment

Name	Address	ID/FEI	Business Operations
Kesin Pharma Corporation		117447816	repack(81033-103)

Establishment

Name	Address	ID/FEI	Business Operations
Kesin Pharma Corporation		119132647	repack(81033-103)

Revised: 12/2024

KESIN PHARMA CORPORATION