

DEXTROMETHORPHAN HBR AND GUAIFENESIN- dextromethorphan hbr and guaifenesin liquid
KESIN PHARMA CORPORATION

Dextromethorphan HBr and Guaifenesin Oral Solution

Dextromethorphan HBr and Guaifenesin Oral Solution

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

Active Ingredients - 5mL (1 teaspoonful)	Purposes
Guaifenesin 100 mg	Expectorant
Dextromethorphan 5 mg	Cough Suppressant

Inactive Ingredients

Trisodium citrate Dihydrate, Citric Acid Anhydrous, USP Xanthan Gum Sodium Benzoate, NF Glycerin 99.7%, USP Propylene Glycol Sucralose Powder Sodium Saccharin, USP Sorbitol Solution 70%, Non-Crystallizable Sodium Artificial Mixed Berry Flavor Purified Water

Uses

- Temporarily relieves cough due to minor throat and bronchial irritations 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 and 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 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.

Directions

- 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

Other information

- **Each teaspoonful contains: sodium 4 mg**
- Store at 20° - 25°C (68° - 77°F)
- Alcohol/sugar free
- Clear, mixed berry flavored solutions supplied in the following oral dosage forms:
NDC 81033-213-05 (unit dose cups of 5mL) and NDC 81033-213-10 (unit dose cups of 10mL)

QUESTIONS OR COMMENTS

Call 1-833-537-4679

PRINCIPAL DISPLAY PANEL - 5 mL Unit Dose Cup Label

NDC 81033-213-50

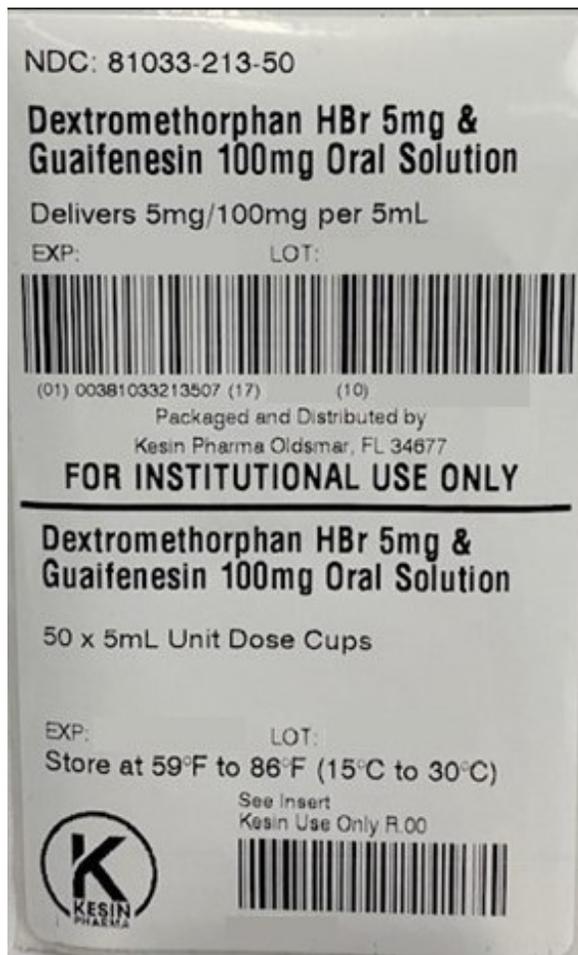
Dextromethorphan HBr and Guaifenesin Oral Solution

Delivers 5mg/100mg per 5mL

FOR INSTITUTIONAL USE ONLY

50 X 5 mL Unit Dose Cups

Store at 59°F to 86°F (15°C to 30°C)



PRINCIPAL DISPLAY PANEL - 10 mL Unit Dose Cup Label

NDC 81033-213-51

Dextromethorphan HBr and Guaifenesin Oral Solution

Delivers 10mg/200mg per 10mL

FOR INSTITUTIONAL USE ONLY

50 X 10 mL Unit Dose Cups

Store at 59°F to 86°F (15°C to 30°C)

NDC: 81033-213-51

Dextromethorphan HBr 10mg & Guaifenesin 200mg Oral Solution

Delivers 10mg/200mg per 10mL

EXP: LOT:



(01) 00381033213514 (17) (10)

Packaged and Distributed by
Kesin Pharma Oldsmar, FL 34677

FOR INSTITUTIONAL USE ONLY

Dextromethorphan HBr 10mg & Guaifenesin 200mg Oral Solution

50 x 10mL Unit Dose Cups

EXP: LOT:
Store at 59°F to 86°F (15°C to 30°C)

See Insert
Kesin Use Only R.00



DEXTROMETHORPHAN HBR AND GUAIFENESIN

dextromethorphan hbr and guaifenesin liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81033-213
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	5 mg in 5 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	

GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KOOR)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	BERRY (Mixed Berry Flavor)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81033-213-50	50 in 1 CARTON	11/15/2023	
1		5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
2	NDC:81033-213-51	50 in 1 CARTON	11/15/2023	
2		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	11/15/2023	

Labeler - KESIN PHARMA CORPORATION (117447816)

Revised: 11/2023

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