DIABETIC TUSSIN DM- dextromethorphan hydrobromide and guaifenes in liquid Carilion Materials Management

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

Active ingredients (in each 5 mL)

Dextromethorphan HBr 10 mg

Guaifenesin 100 mg

Purposes

Cough Suppressant

Expectorant

Uses

- temporarily relieves cough
- helps loosen phlegm (mucus) and thin bronchial secretions to rid bronchial passageways of bothersome mucus

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 two 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

- a cough that occurs with too much phlegm (mucus)
- a chronic cough that lasts or 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 occurs with fever, rash, or headache that lasts

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

- take every 4 hours
- do not exceed 6 doses in 24 hours

adults & children 12 years & over	10 mL (2 teaspoonfuls)
children 6 years to under 12 years	5 mL (1 teaspoonful)
children 2 years to under 6 years	2.5 mL (½ teaspoonful)
children under 2 years	ask a doctor

Other information

Phenylketonurics: contains phenylalanine 8.4 mg per teaspoonful (5 mL)

Storage

- store at room temperature 20-25°C (68-77°F)
- keep tightly closed

Inactive ingredients

Acesulfame potassium, artificial cherry flavor, artificial vanilla flavor, aspartame, hypromellose, menthol, methylparaben, potassium sorbate, purified water. Citric acid may be used to adjust pH.

Questions and comments?

Call **1-800-899-3116**, Mon-Thurs 9:00 am - 5:00 pm EST, Fri 9:00 am - 2:30 pm EST.

Serious side effects associated with use of this product may be reported to this number.

HOW SUPPLIED

Product: 68151-0062

NDC: 68151-0062-1 5 mL in a CUP, UNIT-DOSE

DIABETIC TUSSIN DM (DEXTROMETHORPHAN HYDROBROMIDE AND GUAIFENESIN) LIQUID



DIABETIC TUSSIN DM

dextromethorphan hydrobromide and guaifenesin liquid

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:68151-0062(NDC:61787-062)

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 5 mL	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL	

Inactive Ingredients		
Ingredient Name	Strength	
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)		
CHERRY (UNII: BUC519595W)		
VANILLA (UNII: Q74T35078H)		
ASPARTAME (UNII: Z0H242BBR1)		
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)		
MENTHOL, UNSPECIFIED FORM (UNII: L7T10 EIP3A)		
METHYLPARABEN (UNII: A2I8C7HI9T)		
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)		
WATER (UNII: 059QF0KO0R)		
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)		

ı	Packaging				
	#	# Item Code Package Description		Marketing Start Date	Marketing End Date
	1	NDC:68151-0062-1	5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product	12/28/2017	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	05/01/1997	

Labeler - Carilion Materials Management (079239644)

Establishment				
Name	Address	ID/FEI	Business Operations	
Carilion Materials Management		079239644	REPACK(68151-0062)	