DIABETIC TUSSIN DM- dextromethorphan hydrobromide and guaifenesin liquid
MEDTECH PRODUCTS 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.

DiabeticTussin DM 61787-513

Drug Facts

Active ingredients (in each 10 mL)

Dextromethorphan HBr 20 mg

Guaifenesin 200 mg

Purposes

Cough Suppressant

Expectorant

Uses

- temporarily relieves cough caused by the common cold or inhaled irritants
- 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	10 mL (2 teaspoonfuls)
Children under 12 years	Ask a doctor

Other information

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

Storage

- store at room temperature 20-25ºC (68-77ºF)
- 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 **1-800-579-8327**, serious side effects associated with use of this product may be reported to this number.

Package Principal Display Panel

SUGAR & ALCOHOL FREE!

Specifically Formulated for Diabetics

Diabetic Tussin® DM

Dextromethorphan HBr 20 mg (Cough Suppressant)

Guaifenesin 200 mg (Expectorant)

COUGH & CHEST CONGESTION

Relieves

- Mucus
- Coughs
- Soothes Throat
- Chest Congestion

4 Fl. Oz. (118 mL)

DIABETIC TUSSIN DM

dextromethorphan hydrobromide and guaifenesin liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61787-513
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
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
CHERRY (UNII: BUC5I9595W)	
VANILLA (UNII: Q74T35078H)	
ASPARTAME (UNII: Z0H242BBR1)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
WATER (UNII: 059QF0KO0R)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61787-513-04	1 in 1 BOX	02/01/2020	
1		118 mL in 1 BOTTLE; 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	02/01/2020	

Labeler - MEDTECH PRODUCTS INC (114707784)

Establishment

Name	Address	ID/FEI	Business Operations
Akorn Operating Company LLC (dba Akorn)		117696873	manufacture(61787-513)

Revised: 3/2022 MEDTECH PRODUCTS INC