

DIABETIC TUSSIN DM- dextromethorphan hydrobromide and guaifenesin liquid

Health Care Products

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

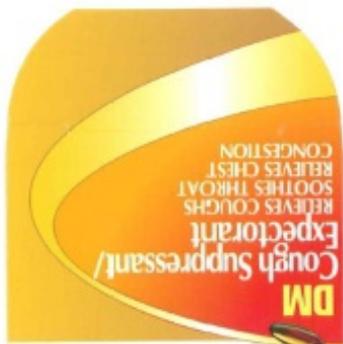
Acesulfame potassium, artificial cherry flavor, artificial vanilla flavor, aspartame, hypromellose, menthol, methylparaben, potassium sorbate, purified water. Citric acid may be used to adjust pH.

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.

Package Principal Display Panel



Diabetic Tussin[®]
Liquid

Diabetic Tussin[®]
Cough Suppressant/Expectorant

Drug Facts

Active ingredients (in each 5 mL)

Dextromethorphan HBr 10 mg	Cough Suppressant
Guafenesin 100 mg	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.

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL AROUND BOTTLE CAP IS BROKEN OR MISSING.

SAVE CARTON FOR COMPLETE DRUG FACTS



Diabetic Tussin[®]
Cough Suppressant/Expectorant

Drug Facts (continued)

Directions

- take every 4 hours
 - do not exceed 6 doses in 24 hours
- | | |
|------------------------------------|-----------------------|
| adults & children 12 years & over | 10 mL (2 teaspoons) |
| children 6 years to under 12 years | 5 mL (1 teaspoon) |
| children 2 years to under 6 years | 2.5 mL (1/2 teaspoon) |
| children under 2 years | ask a doctor |

Other information

- Phenylethanolamines:** contains phenylalanine 8.4 mg per teaspoonful (5 mL)
- store at room temperature 20-25° C (68-77° F)
- keep tightly closed

Inactive ingredients

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

Questions or 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.

Manufactured by: **hcp** MADE IN THE USA
Health Care Products
Diabetes Care Division, a division of
Hi-Tech Pharmaceutical Co., Inc.
Antisville, NY 11701
Visit us online at www.diabeticproducts.com

PERSONS WITH DIABETES – CONSULT YOUR DOCTOR OR PHARMACIST BEFORE USING ANY MEDICATION OR DIETARY SUPPLEMENT

THIS PRODUCT DOES NOT CONTAIN ANY MEDICATION TO IMPROVE OR RELIEVE DIABETES

Ref # 002-04 4/08

Style # 002-04-12

The Very Best
Multi-Vitamin for
those with Diabetes
See why at
www.diabeticproducts.com

NDC 61787-062-04

Diabetic Tussin[®]
Liquid

Diabetic Tussin[®]
Liquid

DM Cough Suppressant/Expectorant

RELIEVES COUGHS
SOOTHES THROAT
RELIEVES CHEST CONGESTION

Liquid

NO Sodium Dye Codeine Sorbitol Fructose

SUGAR & ALCOHOL FREE!

SAFE FOR DIABETICS

4 FL OZ (118mL)

DM Cough Suppressant/Expectorant

RELIEVES COUGHS
SOOTHES THROAT
RELIEVES CHEST CONGESTION

Relieves Coughs
Soothes Throat
Relieves Chest Congestion

The Diabetic Tussin[®] Difference:

All of our products are specifically formulated for diabetics and those on sugar or sodium restricted diets.

SUGAR RESTRICTED DIET: This product is 100% free from sugar, alcohol, honey, fructose, & sorbitol.

SODIUM RESTRICTED DIET: This product is 100% free from sodium. This product is ALSO 100% FREE FROM narcotics, decongestants, and dyes.

Your doctor or pharmacist is your best source of information on any of our products for diabetics.

MADE IN THE USA



NDC 61787-062-04
Diabetic Tussin[®] DM
Cough Suppressant / Expectorant
Relieves Coughs
Soothes Throat

Relieves Chest Congestion

Liquid

No Sodium, Dye, Codeine, Sorbitol, Fructose

Sugar & Alcohol Free!

Safe for Diabetics

4 Fl. Oz. (118 mL)

DIABETIC TUSSIN DM

dextromethorphan hydrobromide and guaifenesin liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61787-062
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	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: BUC5I9595W)	
VANILLA (UNII: Q74T35078H)	
ASPARTAME (UNII: Z0H242BBR1)	
HYPROMELLOSE (UNII: 3NXW29V3WO)	
MENTHOL (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:61787-062-04	1 in 1 BOX		
1		118 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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OTC monograph final	part341	05/01/1997	
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Labeler - Health Care Products (101196749)

Registrant - Hi-Tech Pharmacal Co., Inc. (101196749)

Establishment			
Name	Address	ID/FEI	Business Operations
Hi-Tech Pharmacal Co., Inc.		101196749	MANUFACTURE

Revised: 9/2010

Health Care Products