

**DIABETIC TUSSIN NIGHTTIME COLD AND FLU- acetaminophen,
dextromethorphan hbr, and diphenhydramine hcl 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.

Diabetic Tussin Nighttime Cold and Flu 61787-516

Drug Facts

Active ingredients (in each 10 mL)

Acetaminophen 650 mg

Dextromethorphan HBr 20 mg

Diphenhydramine HCl 25 mg

Purposes

Pain Relief

Cough Suppressant

Antihistamine

Uses

temporarily relieves common cold/flu symptoms including:

- cough due to minor throat and bronchial irritation
- sore throat
- headache
- minor aches and pains
- muscular aches
- fever
- runny nose and sneezing

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if

- adults take more than 6 doses in 24 hours, which is the maximum daily amount
- child takes more than 5 doses in 24 hours, which is the maximum daily amount
- taken with other drugs containing acetaminophen
- adult has 3 or more alcoholic drinks everyday while using this product

Sore throat warning: If sore throat is severe, persists for more than two days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Do not use

Ask a doctor before use if you have

- liver disease
- glaucoma
- a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to enlargement of the prostate gland
- cough that occurs with too much phlegm (mucus)
- a chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema

Ask a doctor or pharmacist before use

if the user is taking the blood thinning drug warfarin, tranquilizers or sedatives.

When using this product:

- you may get very drowsy
- avoid alcoholic drinks
- alcohol, sedatives and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in small children

Stop use and ask a doctor if

- redness or swelling is present
- fever gets worse or lasts more than 3 days
- new symptoms occur
- pain or cough gets worse or lasts more than 5 days (children) or 7 days (adults)
- cough comes back or occurs with 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. Prompt medical attention is critical even if you do not notice any signs or symptoms.

Directions

- take every 4 to 6 hours
 - do not exceed more than 6 doses in 24 hours for adults and children over 12 years of age
-

Adults	10 mL (2 teaspoons)
Children under 12 years	ask a doctor

Other information

- Store at room temperature 20-25°C (68-77°F)

Inactive ingredients

Acesulfame potassium, artificial raspberry flavor, hypromellose, menthol, methylparaben, polyethylene glycol, potassium sorbate, propylene glycol, purified water, and sucralose. Citric acid may be used to adjust pH.

Questions or comments?

Call: **1-800-579-8327**, serious side effects associated with use of this product may be reported to this number.

Package/Label Principal Display Panel

SUGAR & ALCOHOL FREE!

Specifically Formulated for Diabetics

Diabetic Tussin®

NIGHTTIME

COLD & FLU

Acetaminophen (Pain Relief)

Dextromethorphan HBr (Cough Suppressant)

Diphenhydramine HCl (Antihistamine)

Relieves:

- Cough
- Sore throat
- Runny nose & sneezing
- Minor aches & pains
- Headache
- Fever

Improved Berry Flavor

4 FL OZ (118 mL)



Drug Facts

Active Ingredients **Purposes**
(in each 10 mL)
Acetaminophen 400 mg Pain Relief
Dextromethorphan Hbr 20 mg, Cough Suppressant
Diphenhydramine HCl 25 mg Antihistamine

Uses

Temporarily relieves common cold/flu symptoms including: •cough due to minor throat and bronchial irritation •sore throat •headache •minor aches and pains •fever •runny nose and sneezing

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if •adults take more than 6 doses in 24 hours, which is the maximum daily amount •child takes more than 5 doses in 24 hours, which is the maximum daily amount •take with other drugs containing acetaminophen •adult has 2 or more alcoholic drinks every day while using this product

See throat warning: If sore throat is severe, persists for more than two days, is accompanied or followed by fever, headache, rash, hoarseness, or vomiting, consult a doctor promptly

Do not use: •with any other drug containing acetaminophen (prescription or nonprescription), if you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

•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. •with any other product containing diphenhydramine, even one used on the skin

Ask a doctor before use if you have: •liver disease •glaucoma •a breathing problem such as emphysema or chronic bronchitis •trouble urinating due to enlargement of the prostate gland •cough that occurs with too much phlegm (mucus) •a chronic cough that lasts or re-occurs with smoking, asthma, chronic bronchitis, or emphysema

* U.S. News & World Report & Pharmacy Times, 2021-2022

Drug Facts (continued)

Ask a doctor or pharmacist before use if the user is taking the blood thinning drug warfarin, tranquilizers or sedatives.

When using this product: •you may get very drowsy •avoid alcoholic drinks •alcohol, sedatives and tranquilizers may increase drowsiness •do not drink when driving a motor vehicle or operating machinery •responsibility may occur, especially in small children

Stop use and ask a doctor if: •dizziness or swelling is present •fever gets worse or lasts more than 3 days •new symptoms occur •pain or cough gets worse or lasts more than 5 days (children) or 7 days (adults) •cough comes back or occurs with rash or headache that lasts as 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. Prompt medical attention is critical even if you do not notice any signs or symptoms.

Directions

•take every 4 to 6 hours •do not exceed more than 6 doses in 24 hours for adults and children over 12 years of age.

Adults: 10 mL (2 teaspoon)
Children under 12 years: ask a doctor

Other information

Store at room temperature 20° to 25° C (68° to 77° F)

Inactive ingredients

acetulfone potassium, artificial raspberry flavor, hydroxytoluene, menthol, methylparaben, polyethylene glycol, propylene glycol, potassium sorbate, purified water, and saccharin. Citric acid may be used to adjust pH.

Questions or comments?

Call 1-800-525-8307. Serious side effects associated with use of this product may be reported to this number.

SAVE CARTON FOR COMPLETE DRUG FACTS. TAMPER EVIDENT FOR YOUR PROTECTION THIS BOTTLE HAS A SAFETY SEAL AROUND THE CAP OF THE BOTTLE NECK AND UNDER THE CAP.

SUGAR FREE!
FOR PEOPLE WITH DIABETES

Diabetic Tussin.

THE
Diabetic Tussin.
DIFFERENCE

Specifically Formulated
FOR PEOPLE WITH DIABETES

EVERYTHING YOU WANT AND NOTHING YOU DON'T

DECONGESTANT FREE

MADE WITHOUT:

SUGAR - ALCOHOL
SODIUM - SORBITOL
FRUCTOSE - GLUTEN
DYES OR ASPARTAME

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.

NIGHTTIME Cold & Flu

Acetaminophen (Pain Relief)
Dextromethorphan Hbr (Cough Suppressant)
Diphenhydramine HCl (Antihistamine)



- RELIEVES
- cough
- sore throat
- fever
- minor aches & pains
- headache
- runny nose & sneezing

BERRY

FL OZ (118 mL)

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DIABETIC TUSSIN NIGHTTIME COLD AND FLU

acetaminophen, dextromethorphan hbr, and diphenhydramine hcl liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61787-516
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 10 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 10 mL
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg in 10 mL

Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYETHYLENE GLYCOL 400 (UNII: B6978945GQ)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
RASPBERRY (UNII: 4N14V5R27W)	
WATER (UNII: 059QF0K00R)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	RASPBERRY (artificial raspberry flavor)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61787-516-04	1 in 1 CARTON	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
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Akorn Operating Company LLC (dba Akorn)

117696873

manufacture(61787-516)

Revised: 3/2022

MEDTECH PRODUCTS INC