

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

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Diphenhydramine HCl 12.5 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

- 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 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
- 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. 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 5 doses in 24 hours for children under 12 years of age
- do not exceed more than 6 doses in 24 hours for adults and children over 12 years of age

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

Other information

- **Phenylketonurics:** contains phenylalanine 8.4 mg per teaspoonful (5 mL)
- Store at room temperature 20-25°C (68-77°F)

Inactive ingredients

Acesulfame potassium, aspartame, citric acid, hypromellose, menthol, methylparaben, natural & artificial orange flavor, polyethylene glycol, potassium sorbate, propylene glycol, purified water. Sodium citrate 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.

Rev. 452:04 12/11

Package/Label Principal Display Panel



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

Diabetic Tussin®

Nighttime Cold & Flu

Drug Facts

Active ingredients (in each 5 mL)	Purposes
Acetaminophen 325 mg	Pain Relief
Dextromethorphan HBr 10 mg	Cough Suppressant
Diphenhydramine HCl 12.5 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
 ■ 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
 ■ 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 as occurs with smoking, asthma, chronic bronchitis, or emphysema

Diabetic Tussin®

Nighttime Cold & Flu

Drug Facts (continued)

Warnings (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
 ■ 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
 ■ 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. 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 5 doses in 24 hours for children under 12 years of age	
do not exceed more than 6 doses in 24 hours for adults and children over 12 years of age	
adults & children 12 years & over	10 mL (2 teaspoonfuls)
children 6 years to under 12 years	5 mL (1 teaspoonful)
children under 6 years	ask a doctor

TAMPER EVIDENT: FOR YOUR PROTECTION, THIS BOTTLE HAS A SAFETY SEAL AROUND THE NECK OR UNDER THE CAP.

Rev # 452-04 12/11 Style # 452-004-12

NDC 61787-452-04

Diabetic Tussin®

DECONGESTANT FREE

Nighttime Cold & Flu

FEVER, HEADACHE
BODY ACHES
COUGHS
SNEEZING
RUNNY NOSE

Liquid

NO Sodium Sorbitol Fructose & Dyes

**ACETAMINOPHEN
DEXTROMETHORPHAN HBr
DIPHENHYDRAMINE HCl**

**SAFE FOR DIABETICS
SUGAR & ALCOHOL FREE!
GLUTEN FREE**

4 FL. OZ. (118mL)

Drug Facts (continued)

Other information
 ■ Phenylephrine: contains phenylephrine & 4 mg per teaspoonful (5 mL)
 ■ Store at room temperature 20-25°C (68-77°F)

Inactive ingredients
 Acesulfame potassium, aspartame, citric acid, hypromellose, menthol, methylparaben, natural & artificial orange flavor, polyethylene glycol, potassium sorbate, propylene glycol, purified water. Sodium citrate 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.

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

SAVE CARTON FOR COMPLETE DRUG FACTS

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.

Manufactured by: © Health Care Products Diabetes Care Division, A Division of Hi-Tech Pharmaceutical Co., Inc. Amityville, New York 11701

Visit us online at www.diabeticproducts.com

MADE IN THE USA

NDC 61787-452-04
Diabetic Tussin®
 DECONGESTANT FREE

Nighttime**Cold & Flu**

FEVER, HEADACHE

BODY ACHES

COUGHS

SNEEZING

RUNNY NOSE

Liquid

NO

Sodium

Sorbitol

Fructose

& Dyes

*ACETAMINOPHEN**DEXTROMETHORPHAN HBr**DIPHENHYDRAMINE HCl**SAFE FOR DIABETICS**SUGAR & ALCOHOL FREE!**GLUTEN FREE*

4 FL OZ (118 mL)

DIABETIC TUSSIN NIGHTTIME COLD AND FLU

acetaminophen, dextromethorphan hbr, and diphenhydramine hcl liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61787-452
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg in 5 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 5 mL
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	12.5 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ASPARTAME (UNII: Z0H242BBR1)	
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
HYPROMELLOSE 2910 (4000 MPA.S) (UNII: RN3152OP35)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	

Product Characteristics

Color	BROWN (clear, colorless to light brown)	Score	
Shape		Size	
Flavor	ORANGE (natural & artificial orange flavor) , MENTHOL	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61787-452-04	1 in 1 CARTON	08/01/2010	
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:61787-452-08	1 in 1 CARTON	08/01/2010	
2		237 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	08/01/2010	

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(61787-452)