

NITE TIME COLD AND COUGH- diphenhydramine hydrochloride and phenylephrine hydrochloride solution

Accudial Pharmaceutical, 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.

Nite Time Cold & Cough

Drug Facts

Active ingredient (in each 5 mL = 1 teaspoon)	Purpose
Diphenhydramine HCl, USP 6.25 mg	Antihistamine/Cough suppressant
Phenylephrine HCl, USP 2.5 mg	Nasal decongestant

Uses

Temporarily relieves

- sneezing
- itchy nose or throat
- runny nose
- itchy, watery eyes due to hay fever
- nasal and sinus congestion
- cough due to minor throat and bronchial irritation as may occur with a cold.

Warnings

Do not use in a child under 6 years of age

- in a child who is 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 the child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product
- with any other product containing diphenhydramine, even one used on skin
- for the purpose of making your child sleepy.

Ask a doctor before use if the child has heart disease

- high blood pressure thyroid disease
- diabetes
- glaucoma cough that occurs with too much phlegm (mucus)
- chronic cough that lasts, or as occurs with asthma
- a breathing problem such as chronic bronchitis.

Ask a pharmacist before use if the child is taking sedatives or tranquilizers.

When using this product

- **do not exceed recommended dosage** marked drowsiness may occur
- sedatives and tranquilizers may increase drowsiness excitability may occur, especially in children.

Stop use and ask a doctor if nervousness, dizziness, or sleeplessness occurs.

- symptoms do not improve within 7 days or occur with a fever.

- cough persists for more than 7 days, comes back, or occurs with a fever, rash, or persistent headache. These could be signs of a serious condition.

Consult your pharmacist or health care provider for any appropriate, additional dosage delivery device necessary for use when a physician recommends a dose that is different than the doses that appear on the dosage delivery device that accompanies this product.

Age (yr)	Dose (TSP)
under 6 yrs.	ask a doctor
6 to under 12	2 TSP
or as directed by a doctor	

TSP = teaspoon

Keep out of reach of children.

Overdose warning

Taking more than the recommended dose (overdose) may cause liver damage. In the case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222). Prompt medical attention is critical, even if you do not notice any signs or symptoms.

Other information

- **each teaspoon contains: sodium 9 mg**
- store between 20°-25°C (68°-77°F)
- **tamper evident:** do not use if foil seal over the mouth of the bottle is torn, broken, or missing.

Directions

- may be given every 4 hours
- do not use more than 6 times in 24 hours
- use only enclosed dosing cup to dose this product. Do not use any other dosing device.

Inactive ingredients

artificial flavor, benzoic acid, citric acid, EDTA disodium dihydrate, FD&C blue #1, FD&C red #40, propylene glycol, purified water, sodium citrate, sodium saccharin, sorbitol.

Questions?

877-434-2036

Distributed by: AccuDial® Pharmaceutical, Inc.
Palm Beach Gardens, FL 33408

PRINCIPAL DISPLAY PANEL - 118 mL Bottle Label

ACCUDIAL®

Children's

Nite Time

Cold and Cough

Diphenhydramine

(Antihistamine/Cough Suppressant)

Phenylephrine HCl (Nasal Decongestant)

**Relieves Cough • Runny Nose
Stuffy Nose • Itchy Throat**

**Earth-Friendly
Package!**

For Ages 6 yrs to under 12 yrs

Tamper Evident

Compares to Children's Triaminic®
Night Time Cold & Cough

**GRAPE
FLAVOR**

NDC 45014-159-04
4 FL. OZ. (118 mL)

▶▶▶ TURN LABEL FOR DRUG FACTS ▶▶▶ TURN LABEL FOR DRUG FACTS ▶▶▶ TURN LABEL FOR DRUG FACTS ▶▶▶

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U.S. Patent Nos. 6,276,533 and 7,172,668.

Drug Facts (continued)

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6 yrs to under 12 yrs under 6 yrs

2 TSP Ask a Doctor



5346-0712 202
Go Green Nite Time Cold & Cough

NITE TIME COLD AND COUGH

diphenhydramine hydrochloride and phenylephrine hydrochloride solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:450 14-159
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
Diphenhydramine Hydrochloride (UNII: TC2D6JAD40) (Diphenhydramine - UNII:8GTS82S83M)	Diphenhydramine Hydrochloride	6.25 mg in 5 mL
Phenylephrine Hydrochloride (UNII: 04JA59TNSJ) (Phenylephrine - UNII:1WS297W6MV)	Phenylephrine Hydrochloride	2.5 mg in 5 mL

Inactive Ingredients	
Ingredient Name	Strength
Benzoic Acid (UNII: 8SKN0B0MIM)	
Citric Acid Monohydrate (UNII: 2968PHW8QP)	
Edetate Disodium (UNII: 7FLD91C86K)	
FD&C Blue No. 1 (UNII: H3R47K3TBD)	
FD&C Red No. 40 (UNII: WZB9127XOA)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Water (UNII: 059QF0K00R)	
Sodium Citrate (UNII: 1Q73Q2JULR)	
Saccharin Sodium (UNII: SB8ZUX40TY)	
Sorbitol (UNII: 506T60A25R)	

Product Characteristics			
Color	PURPLE	Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:450 14-159-04	118 mL in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	02/01/2013	

Labeler - Accudial Pharmaceutical, Inc. (831999201)

Establishment				
Name	Address	ID/FEI	Business Operations	
Dis. Pharm			ANALYSIS (450 14-159)	MANUFACTURE (450 14-159)
			RELABEL (450 14-159)	REPACK (450 14-159)

BIO-Pharm, Inc.	801652546	ANALYSIS(45014-159), MANUFACTURE(45014-159), RE LABEL(45014-159), REPACK(45014-159)
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Revised: 2/2013

Accudial Pharmaceutical, Inc.