NITE TIME COLD AND COUGH- diphenhydramine hydrochloride and phenylephrine hydrochloride liquid
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.

Children's
ACCUDIAL

NITE TIME COLD & COUGH

Drug Facts

Active ingredients (in each 5 mL, 1 teaspoonful)	***Purposes***
Diphenhydramine HCl 6.25 mg	Antihistamine/Cough suppressant
Phenylephrine HCl 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 doctor or 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.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- may be given every 4 hours. Do not give more than 6 doses in 24 hours unless directed by a doctor.
- to find right dose, use rotating bottle label to dose by weight; otherwise, use chart below to dose by age.
- specifically designed for use with enclosed dosing spoon. Use only enclosed dosing spoon to dose this product. Do not use any other dosing device.

children under 6 years of age	do not use
children 6 to under 12 years of age	1-2 tsp. (5-10 mL)

Other information

- each teaspoonful contains: **sodium 4 mg**
- store at controlled room temperature 20°-25°C (68°-77°F)

Inactive ingredients

artificial flavor, benzoic acid, citric acid, disodium edetate, FD&C blue no. 1, FD&C red no. 40, propylene glycol, purified water, sodium citrate, sodium saccharin, sorbitol.

Questions?

877-434-2036

PRINCIPAL DISPLAY PANEL - 118 mL Carton

CHILDREN'S
ACCU**DIAL**

ROTATING DOSING LABEL

Nite Time
Cold & Cough

ACCURATE DOSING
BY WEIGHT

Diphenhydramine HCl
(Antihistamine/Cough Suppressant

Phenylephrine HCl
(Nasal Decongestant)

Cough Relief
Runny, Stuffy Nose
Itchy Throat

For Ages 6 to under 12

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

GRAPE FLAVOR

4 FL. OZ.
(118 mL)
NDC 45014-154-04

NITE TIME COLD AND COUGH

diphenhydramine hydrochloride and phenylephrine hydrochloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:45014-154
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
Grape (UNII: 6X543N684K)	
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: 059QF0KO0R)	
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:45014-154-04	118 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	11/25/2009	

Labeler - Accudial Pharmaceutical, Inc. (831999201)

Revised: 11/2009 Accudial Pharmaceutical, Inc.