NIGHTTIME COLD AND COUGH CHILDRENS- diphenhydramine hcl, phenylephrine hcl solution
Kroger Company

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.

Kroger Co. Children's NightTime Cold & Cough Drug Facts

Active ingredients (in each 5 mL)

Diphenhydramine HCl 6.25 mg

Phenylephrine HCl 2.5 mg

Purposes

Antihistamine/cough suppressant

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 4 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 your 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
- to make a 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**
- may cause marked drowsiness
- sedatives and tranquilizers may increase drowsiness
- excitability may occur, especially in children

Stop use and ask a doctor if

- nervousness, dizziness or sleeplessness occur
- symptoms do improve within 7 days or occur with fever
- cough persists for more than 7 days, comes back, or occurs with fever, rash or persistent headache. A persistent cough may be a sign 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 (1-800-222-1222).

Directions

- may be given every 4 hours. Do not give more than 6 doses in 24 hours unless directed by a doctor.
- use enclosed dosing cup only. Keep for use with this product only. Do not use any other dosing device.

Age	Dose
children under 4 years of age	**do not use**
children 4 to under 6 years of age	do not use unless directed by a doctor
children 6 to under 12 years of age	10 mL

Other information

- **each 5 mL contains:** sodium 3 mg
- store at 20-25°C (68-77°F)

Inactive ingredients

acesulfame potassium, anhydrous citric acid, edetate disodium, FD&C blue #1, FD&C red #40, flavor, maltitol solution, propylene glycol, purified water, sodium benzoate, sodium citrate

Questions or comments?

1-800-632-6900

Principal Display Panel

COMPARE TO the active ingredients of TRIAMINIC® NIGHT TIME COLD & COUGH

See side panel

OUR PHARMACIST RECOMMENDED

Ages 6 to 12 Years

children's

NightTime

Cold & Cough

Triacting Syrup

Diphenhydramine HCl

Antihistamine/Cough Suppressant

Phenylephrine HCl

Nasal Decongestant

Cough Relief

Runny, Stuffy Nose

Itchy Throat

Grape Flavor

4 FL OZ (118 mL)

NIGHTTIME COLD AND COUGH CHILDRENS

diphenhydramine hcl, phenylephrine hcl solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:30142-021
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**
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
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 BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	

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:30142-021-26	1 in 1 CARTON	08/29/2007	
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	08/29/2007	

Labeler - Kroger Company (006999528)

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