# CHILDRENS COLD AND COUGH NIGHTTIME- diphenhydramine hcl, phenylephrine hcl liquid Family Dollar (FAMILY WELLNESS)

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.

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# **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
  - runny nose
  - itchy nose or throat
  - o itchy, watery eyes due to hay fever
  - nasal and sinus congestion
  - $\circ\,$  cough due to minor throat and bronchial irritations 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
- 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
- excitability may occur, especially in children
- sedatives and tranquilizers may increase drowsiness

# 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 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 (1-800-222-1222) right away.

#### **Directions**

- do not give more than 6 doses in 24 hours unless directed by a doctor.
- mL = milliliter
- measure only with dosing cup provided. Do not use any other dosing device.
- keep dosing cup with product
- shake well before using

Age	Dose
children 6 to under 12 years	10 mL every 4 hours
children 4 to under 6 years	do not use unless directed by a doctor
children under 4 years	do not use

#### Other Information

- each 5 mL contains: sodium 3 mg
- store between 20-25°C (68-77°F). do not refrigerate

• protect from light

# **Inactive ingredients**

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

# Questions or comments?

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

# **Principal Display Panel**

COMPARE TO ACTIVE INGREDIENTS OF CHILDREN'S TRIAMINIC® NIGHTTIME COLD & COUGH\*

Children's

# **Cold & Cough Nighttime**

Diphenhydramine HCL Antihistamine/Cough Suppressant

Phenylephrine HCL Nasal Decongestant

For Ages 6 to 11 Years

- Cough
- Runny, Stuffy Nose
- Itchy Throat

Alcohol-Free

FL OZ (mL)

GRAPE FLAVOR

Dosing Cup Included

\*This product is not manufactured or distributed by GSK, Consumer Healthcare, distributor of Children's Triaminic® NightTime Cold & Cough.

# TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF PRINTED SAFETY SEAL AROUND BOTTLE OR UNDER CAP IS BROKEN OR MISSING.

**DISTRIBUTED BY:** 

MIDWOOD BRANDS, LLC

500 VOLVO PARKWAY

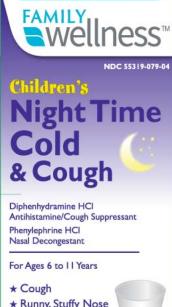
CHESAPEAKE, VA 23320

# Package Label



NOT 100% SATISFIED?

Return package and unused product within 30 days to any Family Dollar store for a refund (with receipt) or exchange.



COMPARE TO THE ACTIVE INGREDIENTS IN CHILDREN' TRIAMINIC'S NIGHT TIME COLD & COUGHS



\* Runny, Stuffy Nose

\* Itchy Throat

4 FL OZ (118 mL)

Alcohol-free

Grape Flavor

Stop use and ask a doctor if ■ nervousness, dizziness, or sleeplessness occurs ■ symptoms do not improve within 7 days or occur with a fever

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SKU 0900574 PLD-J320E FC006063

Lot No.: Exp. Date:

FAMILY WELLNESS Children's Nighttime Cold & Cough

#### CHILDRENS COLD AND COUGH NIGHTTIME

4 FL OZ (118 mL)

Alcohol-free

diphenhydramine hcl, phenylephrine hcl liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55319-079
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
<b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (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: 230V73Q5G9)			
SODIUM BENZOATE (UNII: OJ245FE5EU)			
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)			
EDETATE DISODIUM (UNII: 7FLD91C86K)			
MALTITOL (UNII: D65DG142WK)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
WATER (UNII: 059QF0KO0R)			
FD&C RED NO. 40 (UNII: WZB9127XOA)			
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:55319- 079-04	1 in 1 BOX	11/30/2014	11/30/2025	
1		118 mL in 1 BOTTLE, PLASTIC; 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	11/30/2014	11/30/2025

# Labeler - Family Dollar (FAMILY WELLNESS) (024472631)

Revised: 1/2023 Family Dollar (FAMILY WELLNESS)