

NIGHTTIME COLD AND COUGH CHILDREN- diphenhydramine hcl, phenylephrine hcl liquid ASSURED / DOLLAR TREE (Greenbrier International, 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.

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
 - itchy, watery eyes due to hay fever
 - nasal and sinus congestion
 - 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.
- measure only with dosing cup provided Do not use any other dosing device
- keep dosing cup with product
- mL=mililiter
- 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, anhydrous citric acid, EDTA disodium, FD&C blue #1, FD&C red #40, flavor, maltitol, propylene glycol, purified water, sodium benzoate, trisodium citrate dihydrate

Questions or comments?

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

Principal Display Panel

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

COUGH*

CHILDREN'S

Triacting Night Time Cold & Cough

Diphenhydramine HCl 6.25 mg

Antihistamine / Cough Suppressant

Phenylephrine HCl 2.5 mg

Nasal Decongestant

Relieves Itchy Throat, Cough, Runny Nose & Stuffy Nose

AGES 6-11

ALCOHOL-FREE

Grape flavor

FL OZ (mL)

*This product is not manufactured or distributed by GSK Consumer Healthcare distributor of Children's Triaminic® Night Time Cold and Cough.

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

DISTRIBUTED BY:

GREENBRIER INTERNATIONAL, INC.

500 VOLVO PARKWAY,

CHESAPEAKE, VA 23320

Package Label

COMPARE TO ACTIVE INGREDIENTS IN CHILDREN'S TRIAMINIC® NIGHT TIME COLD & COUGH*

CHILDREN'S NDC 33992-0379-4

Triacting Night Time Cold & Cough

Diphenhydramine HCl 6.25 mg
Antihistamine/Cough Suppressant

Phenylephrine HCl 2.5 mg
Nasal Decongestant

Relieves Itchy Throat, Cough, Runny Nose & Stuffy Nose

AGES 6-11
ALCOHOL-FREE **4 FL OZ (118 mL)**

Grape flavor

Drug Facts TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL AROUND BOTTLE OR UNDER CAP IS BROKEN OR MISSING.

Active ingredients (in each 5 mL)
Diphenhydramine HCl 6.25 mg.....Antihistamine/Cough suppressant
Phenylephrine HCl 2.5 mg.....Nasal decongestant

Purposes
temporarily relieves sneezing, runny nose, itchy nose or throat, itchy, watery eyes due to hay fever, nasal and sinus congestion, cough due to minor throat and bronchial irritations as may occur with a cold

Uses

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 sleep

Ask a doctor before use if the child has heart disease, high blood pressure, thyroid disease, diabetes, glaucoma, a breathing problem such as chronic bronchitis

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L8005021

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500 VOLVO PARKWAY,
CHESAPEAKE, VA 23320

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Drug Facts (continued)

cough that occurs with too much phlegm (mucus), chronic cough that lasts, or as occurs with asthma

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, 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

Drug Facts (continued under label) **PEEL HERE** →

Drug Facts (continued)

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

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

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

ASSURED Children's Triacting Nighttime Cold & Cough

NIGHTTIME COLD AND COUGH CHILDREN			
diphenhydramine hcl, phenylephrine hcl liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:33992-0379
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)			
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			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:33992-0379-4	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/31/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	08/31/2017	

Labeler - ASSURED / DOLLAR TREE (Greenbrier International, Inc.) (610322518)

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Revised: 3/2019

ASSURED / DOLLAR TREE (Greenbrier International, Inc.)