

**CHILDRENS COLD AND COUGH NIGHTTIME- diphenhydramine hcl,
phenylephrine hcl liquid
Safeway, 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 sedative 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=milliliter
- 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 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, 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 **1-888-723-3929** Monday-Friday 7AM-6PM PST

Principal Display Panel

Compare to Children's Triaminic® NightTime Cold & Cough active ingredients*

Children's Nighttime

Cold & Cough Relief

FOR AGES 6-11 YEARS

Diphenhydramine HCl 6.25 mg - Antihistamine/Cough Suppressant

Phenylephrine HCl 2.5 mg - Nasal Decongestant

GRAPE FLAVOR

- Relief of: Cough, runny, stuffy nose itchy throat
- Alcohol-Free

FL OZ (mL)

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

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






DISTRIBUTED BY

BETTER LIVING BRANDS LLC

P.O. BOX 99, PLEASANTON, CA 94566-0009

www.betterlivingbrandsLLC.com

Package Label

<p>Drug Facts (continued)</p> <p>Directions</p> <ul style="list-style-type: none"> 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. <ul style="list-style-type: none"> keep dosing cup with product shake well before using mL = milliliter <table border="1"> <tr> <th>Age</th> <th>Dose</th> </tr> <tr> <td>children 6 to under 12 years of age</td> <td>10 mL every 4 hours</td> </tr> <tr> <td>children 4 to under 6 years of age</td> <td>do not use unless directed by a doctor</td> </tr> <tr> <td>children under 4 years of age</td> <td>do not use</td> </tr> </table> <p>Other information</p> <ul style="list-style-type: none"> each 5 mL contains: sodium 3 mg store between 20-25°C (68-77°F). Do not refrigerate. protect from light <p>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</p> <p>Questions or comments? Call 1-877-753-3925 Monday-Friday 9AM-5PM EST</p>	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	<p>Compare to Children's Triaminic® Night Time Cold & Cough active ingredients*</p> <p>NDC 21130-379-04</p>  <p>Quality Guaranteed</p>	<p>Compare to Children's Triaminic® Night Time Cold & Cough active ingredients*</p> <p>NDC 21130-379-04</p>  <p>Quality Guaranteed</p>	<p>Drug Facts</p> <table border="1"> <tr> <th>Active ingredients (in each 5 mL)</th> <th>Purposes</th> </tr> <tr> <td>Diphenhydramine HCl 6.25 mg</td> <td>Antihistamine/Cough suppressant</td> </tr> <tr> <td>Phenylephrine HCl 2.5 mg</td> <td>Nasal decongestant</td> </tr> </table> <p>Uses</p> <ul style="list-style-type: none"> temporarily relieves <ul style="list-style-type: none"> 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 <p>Warnings</p> <p>Do not use</p> <ul style="list-style-type: none"> 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 <p>Ask a doctor before use if the child has</p> <ul style="list-style-type: none"> 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 <p>Ask a doctor or pharmacist before use if the child is taking sedatives or tranquilizers.</p> <p>When using this product</p> <ul style="list-style-type: none"> do not exceed recommended dosage marked drowsiness may occur excitability may occur, especially in children sedatives and tranquilizers may increase drowsiness <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> 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. <p>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.</p>	Active ingredients (in each 5 mL)	Purposes	Diphenhydramine HCl 6.25 mg	Antihistamine/Cough suppressant	Phenylephrine HCl 2.5 mg	Nasal decongestant
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SIGNATURE CARE Children's Nighttime Cold and Cough Relief Grape Flavor

CHILDRENS COLD AND COUGH NIGHTTIME			
diphenhydramine hcl, phenylephrine hcl liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21130-379
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: 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			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21130-379-04	1 in 1 BOX	12/31/2015	
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	12/31/2015	

Labeler - Safeway, Inc. (009137209)