

**CHILDRENS TRIACTING NIGHTTIME COLD AND COUGH READYIN CASE-
diphenhydramine hcl, phenylephrine hcl liquid
P & L Development, LLC**

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 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 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
- a breathing problem such as chronic bronchitis

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

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

Principal Display Panel

Compare to the active ingredients in Children's Triaminic® Nighttime Cold & Cough

children's triacting nighttime

Cold & Cough

Diphenhydramine HCl 6.25 mg

Phenylephrine HCl 2.5 mg

antihistamine/

cough suppressant

nasal decongestant

relieves:

- cough
- runny, stuffy nose
- itchy throat

for ages 6 to 11

Grape Flavor

FL OZ (mL)

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

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

Manufactured by:

PL Developments

11865 S. Alameda St

Lynwood, CA 90262

Package Label

Drug Facts (continued)

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Dosing Cup Included



Manufactured by:
PL Developments
11865 S. Alameda St
Lynwood, CA 90262



Compare to the active ingredients in **Children's Triaminic® Night Time Cold & Cough®**
NDC 49580-0379-4

children's triacting night time cold & cough

Diphenhydramine HCl 6.25 mg
Phenylephrine HCl 2.5 mg
antihistamine/
cough suppressant
nasal decongestant



relieves:

- cough
- runny, stuffy nose
- itchy throat

for ages 6 to 11 years
alcohol free
4 fl oz (118 mL)



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PLD-A320E FC007681

Lot No.:
Exp. Date:

READYinCASE Children's Triacting Night Time Cold and Cough

CHILDRENS TRIACTING NIGHTTIME COLD AND COUGH
READYINCASE
diphenhydramine hcl, phenylephrine hcl liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49580-0379
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 5 mL	
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	6.25 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)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
MALTITOL (UNII: D65DG142WK)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49580-0379-4	1 in 1 BOX	11/30/2014	
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 Drug	M012	11/30/2014	

Labeler - P & L Development, LLC (101896231)