

CHILDRENS COLD AND COUGH NIGHTTIME- diphenhydramine hcl, phenylephrine hcl liquid

Walgreens

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

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

Children's

Cold & Cough

DIPHENHYDRAMINE HCl / ANTIHISTAMINE / COUGH SUPPRESSANT

PHENYLEPHRINE HCl / NASAL DECONGESTANT

Compare to Children's Triaminic® Night Time Cold & Cough active ingredients^{††}

- Nighttime
- Ages 6 to 11 years

GRAPE FLAVOR

FL OZ (mL)

^{††}This product is not manufactured or distributed by GSK Consumer Healthcare, distributor 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.

DISTRIBUTED BY: WALGREEN CO.

200 WILMOT RD., DEERFIELD, IL 60015

walgreens.com ©2018 Walgreen Co.

Package Label

Drug Facts (continued)
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

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, 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

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

DISTRIBUTED BY: WALGREEN CO., 200 WILMOT RD., DEERFIELD, IL 60015
 100% SATISFACTION GUARANTEED walgreens.com ©2018 Walgreen Co.
 ITEM 357367 W10023-0218-F
 PLD-H320D LB004646 ORG0617-F-R1

Walgreens
children's
Cold & Cough
 NDC 0363-3790-04

DIPHENHYDRAMINE HCl / ANTIHISTAMINE / COUGH SUPPRESSANT
 PHENYLEPHRINE HCl / NASAL DECONGESTANT

Compare to Children's Triaminic® Night Time Cold & Cough active ingredients^{††}

- Nighttime
- Ages 6 to 11 years

4 FL OZ (118 mL) GRAPE FLAVOR

Drug Facts
Active Ingredients (in each 5 mL)

Diphenhydramine HCl 6.25 mg.....	Antihistamine/Cough suppressant
Phenylephrine HCl 2.5 mg.....	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 sleep

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 occur
 ■ 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.

^{††}This product is not manufactured or distributed by GSK Consumer Healthcare, distributor of Children's Triaminic® Night Time Cold & Cough.

WALGREENS Children's Cold & Cough

CHILDRENS COLD AND COUGH NIGHTTIME

diphenhydramine hcl, phenylephrine hcl liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-3790
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: 059QF0K00R)	
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:0363-3790-04	1 in 1 BOX	08/31/2014	
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 FINAL	part341	08/31/2014	

Labeler - Walgreens (008965063)