

COLD AND CONGESTION CHILDRENS NIGHTTIME- diphenhydramine hci, 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 10 mL)

Diphenhydramine HCl 12.5 mg

Phenylephrine HCl 5 mg

Purposes

Antihistamine/Cough suppressant

Nasal decongestant

Uses

- temporarily relieves these symptoms occurring with a cold, hay fever, or other upper respiratory allergies
 - nasal congestion
 - cough
 - runny nose
 - sneezing
 - itchy, watery eyes
 - itching of the nose or throat

Warnings

Do not use

- to sedate a child or to make a child sleepy
- if you are now 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 prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.
- with any other product containing diphenhydramine, even one used on skin.

Ask a doctor before use if you have

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- glaucoma
- trouble urinating due to an enlarged prostate gland
- cough that occurs with too much phlegm (mucus)
- a breathing problem or chronic cough that last or as occurs with smoking, asthma, chronic bronchitis, or emphysema.

Ask a doctor or pharmacist before use if you are

- taking any other oral nasal decongestant or stimulant
- taking sedatives or tranquilizers

When using this product

- **do not use more than directed**
- marked drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

Stop use and ask a doctor if

- you get nervous, dizzy or sleepless
- symptoms do not get better within 7 days or occur with a fever
- cough lasts more than 7 days, comes back, or is accompanied by a fever, rash, or persistent headache.

These could be signs of a serious condition.

If pregnant or breast-feeding,

ask a health professional before use.

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 take more than 6 doses in any 24-hour period
- do not exceed recommended dosage
- measure only with dosing cup provided. Do not use any other dosing device.
- keep dosing cup with product
- mL = milliliter

age	dose
adults and children 12 years and over	20 mL every 4 hours
children 6 to 11 years	10 mL every 4 hours
children under 6 years	do not use

Other information

- **each 10 mL contains:** sodium 6mg
- store at 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 & CONGESTION

DIPHENHYDRAMINE HCl 12.5 mg / ANTIHISTAMINE / COUGH SUPPRESSANT
PHENYLEPHRINE HCl 5 mg / NASAL DECONGESTANT

Compare-to Children's Dimetapp® Nighttime Cold & Congestion active ingredients††

- Nighttime
- Alcohol Free
- 6 years & older

FL OZ (mL)

GRAPE FLAVOR

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 : WALGREEN CO

200 WILMOT RD., DEERFIELD, IL 60015

walgreens.com

Package Label

Drug Facts (continued)
Directions ■ do not take more than 6 doses in any 24 hour period
■ do not exceed recommended dosage ■ measure only with dosing cup provided. Do not use any other dosing device. ■ keep dosing cup with product ■ mL = milliliter

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†† This product is not manufactured or distributed by Pfizer Consumer Healthcare, distributor of Children's Dimetapp® Nighttime Cold & Congestion.
ITEM 904373 W10023-0717-F
PLD-C375A LB004650 ORG0617-F

Walgreens
children's
COLD & CONGESTION
Wal-Tap®
DIPHENHYDRAMINE HCl 12.5 mg /
ANTI-HISTAMINE / COUGH SUPPRESSANT
PHENYLEPHRINE HCl 5 mg /
NASAL DECONGESTANT

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4 FL OZ (118 mL) GRAPE FLAVOR

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WALGREENS Children's Cold & Congestion Grape Flavor

COLD AND CONGESTION CHILDRENS NIGHTTIME

diphenhydramine hci, phenylephrine hcl liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-0058	
Route of Administration	ORAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)		DIPHENHYDRAMINE HYDROCHLORIDE	12.5 mg in 10 mL	
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)		PHENYLEPHRINE HYDROCHLORIDE	5 mg in 10 mL	
Inactive Ingredients				
Ingredient Name			Strength	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
WATER (UNII: 059QF0KO0R)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)				
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)				
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)				
MALTITOL (UNII: D65DG142WK)				
EDETATE DISODIUM (UNII: 7FLD91C86K)				
Product Characteristics				
Color		Score		
Shape		Size		
Flavor	GRAPE	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-0058-04	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/31/2016	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH FINAL	part341	03/31/2016		

Labeler - Walgreens (008965063)