DAYTIME NIGHTTIME COLD AND COUGH CHILDRENS- dextromethorphan hbr, phenylephrine hcl, diphenhydramine hcl, phenylephrine hcl CVS Pharmacy

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 DayTime (in each 5 mL)

Dextromethorphan HBr 5 mg Phenylephrine HCl 2.5 mg

Active ingredients for Nighttime (in each 5 mL)

Diphenhydramine HCl 6.25 mg Phenylephrine HCl 2.5 mg

Purposes for Day Time

Cough suppressant Nasal decongestant

Purpose for Night Time

Antihistamine/Cough suppressant Nasal decongestant

Uses

DAYTIME

- temporarily relieves
 - nasal and sinus congestion
 - o cough due to minor throat and bronchial irritation as may occur with a cold

NIGHTTIME

- 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

DAYTIME

- 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.

NIGHTTIME

- in a child under 4 years of age
- in a child who is taking a prescription monoamine oxidase inhibitor (MAOI) (certan 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 childs 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

DAYTIME

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- cough that occurs with too much phlegm (mucus)
- chronic cough that lasts, or as occurs with asthma

NIGHTTIME

- 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

NIGHTTIME

taking sedatives or tranquilizers.

When using this product

DAYTIME

do not exceed recommended dosage.

NIGHTTIME

- 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

DAYTIME

- 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.

NIGHTTIME

- 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.

Keep out of reach of children.

DAYTIME

In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

NIGHTTIME

In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away

Directions

DAYTIME

- do not give more than 6 doses in any 24-hour period
- 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

age	do not asc
children under 4 years of	do not use
age	hours
children 4 to under 6 years of	5 mL every 4
of age	hours

NIGHTTIME

- 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	10 mL every 4 hours
years of age	10 file every 4 flours
children 4 to under 6	do not use unless
years of age	directed by a doctor
children under 4	do not use
years of age	

Other information

DAYTIME

- each 5 mL contains: sodium 2 mg
- store between 20-25°C (68°-77°F). Do not refrigerate.

NIGHTTIME

- each 5 mL contains: sodium 3 mg
- store between 20-25°C (68-77°F). Do not refrigerate
- protect from light

Inactive ingredients

Inactive ingredients for Day Time

acesulfame potassium, alcohol, benzoic acid, citric acid, disodium EDTA, FD&C red #40, flavor, maltitol, propylene glycol, purified water, sodium citrate

Inactive ingredients for Night Time

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® Day Time Cold & Cough* Daytime

Children's

Cold & Cough

DEXTROMETHORPHAN HBr Cough suppressant

PHENYLEPHRINE HCI Nasal decongestant

Relieves

- Cough
- Stuffy nose

Alcohol 0.14%

For Ages 4 to 11 Years

Cherry Flavor

Dosage cup included

FL OZ (mL)

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

Children's

Nighttime Cold & Cough

DIPHENHYDRAMINE HCI Antihistamine; Cough suppressant

PHENYLEPHRINE HCl Nasal decongestant

Relieves

- Cough
- Runny, stuffy nose
- itchy throat

Alcohol free

For Ages 6 to 11 Years

Grape Flavor

Dosage cup included

FL OZ (mL)

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

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

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

Distributed by: CVS Pharmacy, Inc.

One CVS Drive, Woonsocket, RI 02895

CVS.com

Product Label



CVS HEALTH Daytime and Nighttime Cold and Cough

DAYTIME NIGHTTIME COLD AND COUGH CHILDRENS dextromethorphan hbr, phenylephrine hcl, diphenhydramine hcl, phenylephrine hcl kit Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:69842-422 Packaging # Item Code Package Description Marketing Start Date Marketing End Date

Quantity of Parts		
Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	118 mL
Part 2	1 BOTTLE	118 mL

Part 1 of 2

DAYTIME COLD COUGH CHILDRENS

dextromethorphan hbr, phenylephrine hcl liquid

Product Information

Route of Administration ORAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	5 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)	
ALCOHOL (UNII: 3K9958V90M)	
BENZOIC ACID (UNII: 85KN0B0MIM)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MALTITOL (UNII: D65DG142WK)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	

Product Characteristics		
Color		Score
Shape		Size
Flavor	CHERRY	Imprint Code
Contains		

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		118 mL in 1 BOTTLE; 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	04/30/2018	

Part 2 of 2

NIGHT TIME COLD AND COUGH CHILDREN

diphenhydramine hcl, phenylephrine hcl liquid

Product Information

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	2.5 mg in 5 mL	

Inactive Ingredients	
Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 230V73Q5G9)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MALTITOL (UNII: D65DG142WK)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	

Product Characteristics		
Color	Score	
Shape	Size	

Flavor	GRAPE	Imprint Code
Contains		

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product			

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OTC monograph final	part341	04/30/2018				

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph final	part341	04/30/2018	04/30/2025		

Labeler - CVS Pharmacy (062312574)

Revised: 1/2023 CVS Pharmacy