

**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.*

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**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
  - 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) (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**

#### **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 of age	10 mL every 4 hours
children 4 to under 6 years of age	5 mL every 4 hours
<b>children under 4 years of age</b>	<b>do not use</b>

**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 years of age	10 mL every 4 hours
children 4 to under 6 years of age	do not use unless directed by a doctor
<b>children under 4 years of age</b>	<b>do not use</b>

## **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 HCl 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 HCl 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**

**Children's Cold & Cough Daytime**

**Drug Facts**

**Active Ingredients (in each 5 mL)** **Purposes**  
Dextromethorphan HBr 5 mg. Cough suppressant  
Phenylephrine HCl 2.5 mg. Nasal decongestant

**Uses**  
temporarily relieves  
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 your child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.

**Ask a doctor before use if the child has**  
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

**When using this product, do not exceed recommended dosage.**

**Stop use and ask a doctor if**  
in mucous, diarrhea or sleeplessness occurs  
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 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 of age	10 mL every 4 hours
children 4 to under 6 years of age	5 mL every 4 hours
children under 4 years of age	do not use

**Children's Cold & Cough Daytime (continued)**

**Drug Facts (continued)**

**Other information**  
each 5 mL contains: sodium 7 mg  
store between 20-25°C (68-77°F). Do not refrigerate.

**Inactive Ingredients** acetaminophen potassium, alcohol, benzoic acid, citric acid, disodium EDTA, FD&C red #40, flavor, methylcellulose, polyethylene glycol, purified water, sodium citrate

**Children's Nighttime Cold & Cough**

**Drug Facts**

**Active Ingredients (in each 5 mL)** **Purposes**  
Diphenhydramine HCl 6.25 mg. Cough suppressant  
Phenylephrine HCl 2.5 mg. Nasal decongestant

**Uses**  
temporarily relieves  
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.**

**Children's Nighttime Cold & Cough (continued)**

**Drug Facts (continued)**

**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**  
irritation, diarrhea, 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 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

**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** acetaminophen potassium, citric acid, EFTA disodium, FD&C blue #1, FD&C red #40, flavor, methylcellulose, polyethylene glycol, purified water, sodium benzoate, sodium citrate

**Questions or comments?**  
Call 1-877-753-3825 Monday-Friday 9AM-5PM EST

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

**PARENTS:**  
Learn about how medicine abuse  
www.StopMedicineAbuse.org

**DAY & NIGHT COMBO PACK**

**CVS Health.** Compare to the active ingredients in Children's Triaminic® Day Time Cold & Cough\*  
**Daytime**

**Children's Cold & Cough**  
**DEXTROMETHORPHAN HBr**  
Cough suppressant  
**PHENYLEPHRINE HCl**  
Nasal decongestant

**Relieves:**  
Cough  
Stuffy nose

**Alcohol 0.14%**  
**For Ages 4 to 11 Years**

**Cherry Flavor**  
Dose cup included  
Actual Bottle Size on Side Panel

**CVS Health.** Compare to the active ingredients in Children's Triaminic® Night Time Cold & Cough\*  
**Nighttime**

**Children's Nighttime Cold & Cough**  
**DIPHENHYDRAMINE HCl**  
Antihistamine; Cough suppressant  
**PHENYLEPHRINE HCl**  
Nasal decongestant

**Relieves:**  
Cough  
Runny, stuffy nose  
Itchy throat

**Alcohol free**  
**For Ages 6 to 11 Years**

**Grape Flavor**  
Dose cup included  
Actual Bottle Size on Side Panel

**Package Contains Two Bottles**  
Actual Size

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.

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## 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

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69842-422
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#### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-422-08	1 in 1 KIT; Type 0: Not a Combination Product	04/30/2018	

#### 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
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	5 mg in 5 mL
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 5 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>ACESULFAME POTASSIUM</b> (UNII: 23OV73Q5G9)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>BENZOIC ACID</b> (UNII: 8SKN0B0MIM)	
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>MALTITOL</b> (UNII: D65DG142WK)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>TRISODIUM CITRATE DIHYDRATE</b> (UNII: B22547B95K)	

## Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	CHERRY	<b>Imprint Code</b>	
<b>Contains</b>			

## 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 (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 5 mL

## Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
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		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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	



**Labeler** - CVS Pharmacy (062312574)

Revised: 5/2019

CVS Pharmacy