#### DAYTIME COLD AND COUGH NIGHTTIME COLD AND CONGESTIONbrompheniramine maleate, dextromethorphan hbr, diphenhydramine hcl, phenylephrine hcl CVS

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Children's Daytime Cold & Cough Nighttime Congestion and Cold

#### **ACTIVE INGREDIENT(S) FOR DAYTIME (in each 5 mL)**

Brompheniramine Maleate 1 mg
Dextromethorphan HBr 5 mg
Phenylephrine HCl 2.5 mg

#### **ACTIVE INGREDIENT(S) FOR NIGHTTIME (in each 5 mL)**

Diphenhydramine HCI 6.25 mg Phenylephrine HCI 2.5 mg

#### PURPOSE FOR DAYTIME

Antihistamine Cough suppressant Nasal decongestant

#### **PURPOSE FOR NIGHTTIME**

Antihistamine / Cough suppressant Nasal Decongestant

#### USE(S)

#### **DAYTIME**

- temporarily relieves cough due to minor bronchial irritation as may occur with a cold, and nasal congestion due to the common cold, hay fever or other upper respiratory allergies
- temporarily relieves these symptoms due to hay fever (allergic rhinitis): • sneezing • itching of the nose or throat • runny nose • itchy, watery eyes
- temporarily restores freer breathing through the nose

#### **NIGHTTIME**

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

#### WARNINGS

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#### DO NOT USE

#### **Daytime**

#### 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.

#### **Nighttime**

#### 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 nut 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

#### **DAYTIME**

- heart disease
- glaucoma
- diabetes
- thyroid disease
- high blood pressure
- · difficulty in urination due to an enlarged prostate gland
- cough that occurs wilt too much phlegm (mucus)
- a breathing problem or persistent or chronic cough that lasts such as occurs with smoking, asthma, chronic bronchitis or emphysema

#### **NIGHTTIME**

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

#### ASK A DOCTOR OR PHARMACIST BEFORE USE IF YOU ARE

#### **DAYTIME**

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

#### **NIGHTTIME**

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

#### WHEN USING THIS PRODUCT

#### **DAYTIME**

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

#### **NIGHTTIME**

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

#### STOP USE AND ASK DOCTOR IF

- nervousness, dizziness or sleeplessness occur
- symptoms do not improve within 7 days or are accompanied by fever
- cough lasts more than 7 days, comes back, or is accompanied by 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 right away.

#### **DIRECTIONS**

#### **DAYTIME**

- do not take more than 6 doses in any 24-hour period
- do not exceed recommended dosage
- mL milliliter
- tsp = teaspoon

Age	Dose
adults & children 12 years over	4 tsp (20 mL) every 4 hours
children 6 years to under 12 years	2 tsp (10 mL) every 4 hours
children under 6 years	do not use

#### **NIGHTTIME**

- do not take more than 6 doses in any 24-hour period
- do not exceed recommended dosage
- mL milliliter
- tsp = teaspoon

Age	Dose
adults & children	4 tsp (20 mL) every 4 hours
12 years over	4 tsp (20 mle) every 4 mours
children 6 years to	2 tsp (10 mL) every 4 hours
under 12 years	2 tsp (10 ml) every 4 mours
children under 6 years	do not use

#### OTHER INFORMATION

#### **DAYTIME**

- each teaspoon (tsp) contains: sodium 5 mg
- store at 20-25°C (68-77°F)
- measuring cup provided

#### **NIGHTTIME**

- each teaspoon (tsp) contains: sodium 5 mg
- store at 20-25°C (68-77°F)
- measuring cup provided

#### **INACTIVE INGREDIENTS**

#### **DAYTIME**

anhydrous citric acid, artificial flavor, FD&C blue #1, FD&C red #40, glycerin, propylene glycol, propyl gallate, purified water, sodium benzoate, sodium citrate, sorbitol, sucralose

#### **NIGHTTIME**

anhydrous citric acid, artificial flavor, FD&C blue #1, FD&C red #40, glycerin, propylene glycol, propyl gallate, purified water, sodium benzoate, sodium citrate, sorbitol, sucralose

#### PRINCIPAL DISPLAY PANEL

**DAY/NIGHT PACK** 

**NDC** 51316-939-04

**CVS** Health

Compare to the active Ingredients in Children's Dimetapp® Cold & Cough\* Compare to the active Ingredients in Children's Dimetapp® Nighttime Cold & Cough\*

Children's Daytime Cold & Cough

BROMPHENIRAMINE MALEATE Antihistamine DEXTROMETHORPHAN HBr

## Cough suppressant PHENYLEPHRINE HCI Nasal decongestant **DM Liquid** Relieves: Nasal congestion; Stuffy nose; Runny nose; Sneezes Calms allergy symptoms Soothes Cough Alcohol Free Grape Flavor Ages 6 Years & Over 4 FL OZ (118 mL) Children's Nighttime Congestion & Cold

## **DIPHENYLHYDRAMINE HCI** Cough suppressant; Antihistamine

#### PHENYLEPHRINE HCI

Nasal decongestant

Liquid

Relieves:

Nasal congestion; Stuffy nose;

Runny nose; Sneezes

Calms allergy symptoms Soothes Cough

Alcohol Free

Grape Flavor Ages 6 Years & Over

4 FL OZ (118 mL)

## DAY / NIGHT PACK **BUY TWO & SAVE**



Compare to the active ingredients in Children's Dimetapp® Cold & Cough\*

**♥CVS** Health.

Compare to the active ingredients in Children's Dimetapp® Nighttime Cold & Congestion\*

Grape

# Health.

Grape

### Children's

## **Daytime Cold & Cough**

BROMPHENIRAMINE MALEATE

**Antihistamine** 

**DEXTROMETHORPHAN HBr** 

Cough suppressant

PHENYLEPHRINE HCI

Nasal decongestant

## **DM Liquid**

#### Relieves:

Nasal congestion; Stuffy nose; Runny nose; Sneezes

Calms allergy symptoms Soothes cough



4 FL OZ (118 mL)

## Children's

## Nighttime Congestion & Cold

DIPHENHYDRAMINE HCI

Cough suppressant; Antihistamine

PHENYLEPHRINE HCI

Nasal decongestant

## Liquid

#### Relieves:

Nasal congestion, Stuffy nose, Runny nose; Sneezes

Calms allergy symptoms Soothes cough

Alcohol free



Ages 6 Years & Over

4 FL OZ (118 mL)

brompheniramine maleate, dextromethorphan hbr, diphenhydramine hcl, phenylephrine hcl kit

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:51316-939

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:51316-939- 04	1 in 1 KIT; Type 0: Not a Combination Product	01/31/2025	

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

#### **CHILDRENS DAYTIME COLD AND COUGH**

brompheniramine maleate, dextromethorphan hbr, phenylephrine hcl liquid

Product Information		
Item Code (Source)	NDC:51316-916	
Route of Administration	ORAL	

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
<b>BROMPHENIRAMINE MALEATE</b> (UNII: IXA7C9ZN03) (BROMPHENIRAMINE - UNII: H57G17P2FN)	BROMPHENIRAMINE MALEATE	1 mg in 5 mL
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (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	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
GLYCERIN (UNII: PDC6A3C0OX)		
PROPYL GALLATE (UNII: 8D4SNN7V92)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		

WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	

Product Characteristics			
Color	PURPLE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
<b>1</b> NDC:51316-916-	1 in 1 CARTON		
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 Drug	M012	02/03/2025	

### Part 2 of 2

### **CHILDRENS NIGHTTIME CONGESTION AND COLD**

diphenhydramine hcl, phenylephrine hcl liquid

Product Information	
Item Code (Source)	NDC:51316-919
Route of Administration	ORAL

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
<b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (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
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics			
Color	PURPLE	Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

	Packaging			
7	# Item Code	Package Description	Marketing Start Date	Marketing End Date
:	NDC:51316-919-	1 in 1 CARTON		
:	L	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 Drug	M012	02/03/2025	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	01/31/2025	

## **Labeler -** CVS (062312574)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Guardian Drug Company		119210276	MANUFACTURE(51316-939)	

Revised: 2/2025 CVS