# DAYTIME COLD AND COUGH AND NIGHTTIME COLD AND CONGESTION CHILDRENS- brompheniramine maleate, dextromethorphan hbr, phenylephrine hcl, diphenhydramine hcl, phenylephrine hcl 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.

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#### **DRUG FACTS**

#### Active ingredients for Nighttime (in each 10 mL)

Diphenhydramine HCI 12.5 mg Phenylephrine HCI 5 mg

### Active ingredients for Daytime (in each 10 mL)

Brompheniramine Maleate 2 mg
Dextromethorphan HBr 10mg
Phenylephrine HCl 5 mg

# **Purpose for Nighttime**

Antihistamine / Cough suppressant Nasal Decongestant

# **Purpose for Daytime**

Antihistamine

Cough suppressant

Nasal decongestant

#### Uses

# **Nighttime**

- 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

#### **Daytime**

- temporally relieves cough due to minor throat and bronchial irritation occurring 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)
  - runny nose
  - itchy, watery eyes
  - sneezing
  - itching of the nose or throat
- temporarily restores freer breathing through the nose

#### **Warnings**

#### Do not use

# **Nighttime**

- 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.

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# Ask a doctor before use if you have

# **Nighttime**

- 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 as occurs with smoking, asthma, chronic bronchitis or emphysema

# **Daytime**

- heart disease
- high blood pressure
- thyroid disease

- diabetes
- glaucoma
- trouble urinating due to an enlarged gland
- cough that occurs with too much phlegm (mucus)
- a breathing problem or persistent or chronic cough that lasts such as occurs with smoking, asthma, chronic bronchitis or emphysema

#### Ask a doctor or pharmacist before use if you are

#### **Nighttime**

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

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#### When using these products

#### **Nighttime**

- 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
- excitablity may occur, especially in children

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# Stop use and ask a doctor if

# **Nighttime**

- 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 fever, rash, or persistent headache. These could be signs of a serious condition

# Daytime

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- 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,

#### **Nighttime**

ask a health professional before use.

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# Keep out of reach of children.

#### **Nighttime**

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

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#### **Directions**

#### **Nighttime**

- do not take more than 6 doses in any 24 hours 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 = mililiter

Age	Dose
adults and children 12 years and over	20 mL every 4 hours
childen 6 to under 12 years	10 mL every 4 hours
children under 6 years	do not use

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Children under 6 years	do not use

#### Other information

#### **Nighttime**

- each 10 mL contains: sodium 6 mg
- store at 20-25°C (68-77°F)
- do not refrigerate
- protect from light

#### **Daytime**

- each 10 mL contains: 5 mg
- store between 20-25°C (68-77°F). Do not refrigerate.

#### Inactive ingredients

#### **Nighttime**

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

#### **Daytime**

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

#### Questions or comments?

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

# **Principal Display Panel**

Compare to the active ingredients in Children's Dimetapp® Cold & Cough & Nighttime Cold & Congestion††

# Children's Cold & Congestion Relief

DIPHENHYDRAMINE HCl 12.5 mg /

ANRIHISTAMINE / COUGH SUPPRESSANT

PHENYLEPHRINE HCl 5 mg /

NASAL DECONGESTANT

Nighttime

#### Alcohol Free

• Relieves stuffy nose, runny nose, sneezing, itchy & watery eyes & coughing

AGES 6 YEARS & OLDER

Grape flavor

DOSING CUP INCLUDED

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

††This product is not manufactured or distributed by Pfizer Consumer Healthcare, distributor of Children's Dimetapp® Nighttime Cold & Congestion.

#### **DAYTIME**

Children's Cold & Cough Relief

**BROMPHENIRAMINE MALEATE 2 mg** 

**ANTIHISTAMINE** 

DEXTROMETHORPHAN HBr 10 mg /

**COUGH SUPPRESSANT** 

PHENYLEPHRINE HCI 5 mg/

NASAL DECONGESTANT

Daytime

Alcohol Free

• Relieves nasal congestion, runny nose, itchy & watery eyes, sneezing & coughing

AGES 6 YEARS & OLDER

Grape flavor

# FL OZ (mL)

††This product is not manufactured or distributed by Pfizer Consumer Healthcare, Distributor of Children's Dimetapp® Cold & Cough.

DISTRIBUTED BY: WALGREEN CO.

200 WILMOT RD., DEERFIELD, IL 60015

#### **Product Label**



WALGREENS Children's Cold & Congestion Relief, Children's Cold & Cough Relief

# DAYTIME COLD AND COUGH AND NIGHTTIME COLD AND CONGESTION CHILDRENS

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

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:0363-4590

# **Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-4590- 08	1 in 1 KIT; Type 0: Not a Combination Product	03/04/2022	

#### **Quantity of Parts**

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE, PLASTIC	118 mL
Part 2	1 BOTTLE, PLASTIC	118 mL

#### Part 1 of 2

# **NIGHT TIME COLD AND CONGESTION CHILDRENS**

diphenhydramine hcl, phenylephrine hcl liquid

# **Product Information**

Item Code (Source) NDC:0363-3130

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

Product Characteristics				
Color		Score		
Shape		Size		
Flavor	GRAPE	Imprint Code		
Contains				

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

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

# Part 2 of 2

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

brompheniramine maleate, dextromethorphan hbr, phenylephrine hcl liquid

#### **Product Information**

Item Code (Source) NDC:0363-4580

**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	2 mg in 10 mL
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 10 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 10 mL

Inactive Ingredients	
Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	

Product Characteristics				
Color		Score		
Shape		Size		
Flavor	GRAPE	Imprint Code		
Contains				

F	Packaging					
#	ttem Code	Package Description	Marketing Start Date	Marketing End Date		

1	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	
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Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph final	part341	03/04/2022				

Marketing Information						
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
rt341	03/04/2022					
Δ	Application Number or Monograph Citation	Application Number or Monograph Marketing Start Citation Date				

# Labeler - Walgreens (008965063)

Revised: 3/2022 Walgreens