

**CHILDRENS COLD AND COUGH - brompheniramine maleate,  
dextromethorphan, phenylephrine hcl liquid  
CARDINAL HEALTH 110, LLC. DBA LEADER**

*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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**Leader Childrens Cold and Cough 577**

**ACTIVE INGREDIENTS (in each 10 mL)**

Brompheniramine maleate, USP 2 mg

Dextromethorphan HBr, USP 10 mg

Phenylephrine HCl, USP 5 mg

**PURPOSES**

Antihistamine

Cough Suppressant

Nasal decongestant

**USES**

- 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

**WARNINGS**

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**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, or psychiatric, 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.

### **ASK A DOCTOR BEFORE USE IF YOU HAVE**

- 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 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**

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

### **WHEN USING THIS PRODUCT**

- **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 A 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 (1-800-222-

1222) right away.

## **DIRECTIONS**

- do not take more than 6 doses in any 24-hour period
- measure only with dosing cup provided
- do not exceed recommended dosage
- mL = milliliter

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

## **OTHER INFORMATION**

- **each 10 mL contains:** sodium 10 mg
- store at 20-25°C (68-77°F)
- measuring cup provided

## **INACTIVE INGREDIENTS**

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

## **QUESTIONS OR COMMENTS?**

call (609) 860-2600 Mon - Fri 8:00 am to 4:30 pm est

## **PRINCIPAL DISPLAY PANEL**

### **LEADER**

NDC 70000-0631-1

### **Children's Cold & Cough Liquid**

Brompheniramine Maleate

Dextromethorphan Hydrobromide

Phenylephrine Hydrochloride

Antihistamine

Cough Suppressant

Nasal Decongestant

**Grape**

**Flavor**

**Relieves:**

Stuffy Nose,

Runny Nose,

Sneezing,

Cough

Alcohol-Free

**COMPARE TO CHILDREN'S DIMETAPP®**

**COLD & COUGH**

active ingredients\*

**4 FL OZ (118 mL)**

No Coating Area

COATING FREE AREA

Glue

DO NOT USE IF SEAL UNDER CAP IMPRINTED WITH "SEALED FOR YOUR PROTECTION" IS BROKEN OR MISSING

### Drug Facts

**Active ingredients (in each 10 mL) Purposes**  
Brompheniramine maleate, USP 2 mg.....Antihistamine  
Dextromethorphan HBr, USP 10 mg.....Cough suppressant  
Phenylephrine HCl, USP 5 mg.....Nasal decongestant

#### Uses

- 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

#### 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.

##### Ask a doctor before use if you have

- 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 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

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

##### When using this product

- 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

### Drug Facts (continued)

- excitability may occur, especially in children

#### Stop use and ask a 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 (1-800-222-1222) right away.

#### Directions

- do not take more than 6 doses in any 24-hour period
- measure only with dosing cup provided
- do not exceed recommended dosage
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Age	Dose
adults & children 12 years & over	20 mL every 4 hours
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#### Other information

- each 10 mL contains: sodium 10 mg
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**Inactive ingredients** anhydrous citric acid, artificial flavor, FD&C blue #1, FD&C red #40, glycerin, propylene glycol, propyl galate, purified water, sodium benzoate, sodium citrate, sorbitol, sucralose

**Questions or comments?** call (609) 860-2600 Mon - Fri 8:00 am to 4:30 pm est

\*This product is not manufactured or distributed by Pfizer Consumer Healthcare, the distributor of Children's Dimetapp® Cold and Cough.

KEEP THIS BOX FOR COMPLETE INSTRUCTIONS

LEADER<sup>2</sup>

## Children's Cold & Cough Liquid

Brompheniramine Maleate  
Dextromethorphan HBr  
Phenylephrine HCl  
Antihistamine  
Cough Suppressant  
Nasal Decongestant

LEADER<sup>2</sup>

LEADER<sup>2</sup>

NDC 70000-0631-1

## Children's Cold & Cough Liquid

Brompheniramine Maleate  
Dextromethorphan HBr  
Phenylephrine HCl  
Antihistamine  
Cough Suppressant  
Nasal Decongestant



### Grape Flavor

Relieves:  
Stuffy Nose,  
Runny Nose,  
Sneezing,  
Cough

Alcohol-Free

COMPARE TO CHILDREN'S DIMETAPP® COLD & COUGH active ingredients\*

100% Money Back Guarantee

4 FL OZ (118 mL)

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✓ All LEADER™ Brand Products Have A 100% Money Back Guarantee  
Return to place of purchase if not satisfied.

No Coating Area



LOT:

UNWASHED AREA TO BE LEFT BLANK FOR LOT & EXP. INFORMATION  
EXP:

**Drug Facts** DO NOT USE IF SEAL UNDER CAP IMPRINTED WITH "SEALED FOR YOUR PROTECTION" IS BROKEN OR MISSING.

**Active ingredients (in each 10 mL)** **Purposes**  
 Brompheniramine maleate, USP 2 mg...Antihistamine  
 Dextromethorphan HBr, USP 10 mg...Cough suppressant  
 Phenylephrine HCl, USP 5 mg...Nasal decongestant

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**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)

Drug Facts continued on other panel

**LEADER?**

NDC 70000-0631-1

**Children's Cold & Cough Liquid**

Brompheniramine Maleate  
 Dextromethorphan HBr  
 Phenylephrine HCl  
 Antihistamine | Cough Suppressant  
 Nasal Decongestant

Grape Flavor  
 Relieves:  
 Sneezy Nose,  
 Runny Nose,  
 Sore Throat,  
 Cough

**100% Money Back Guarantee**

**4 FL OZ (118 mL)**

Alcohol-free

**Drug Facts (continued)**

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.

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**Other information** ■ each 10 mL contains: sodium 10 mg ■ store at 20-25°C (68-77°F) ■ measuring cup provided

Keep carton for complete information. MFRM 53041

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 Cardinal Health.

LOT: \_\_\_\_\_  
 EXP: \_\_\_\_\_

## CHILDRENS COLD AND COUGH

brompheniramine maleate, dextromethorphan, phenylephrine hcl liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70000-0631
<b>Route of Administration</b>	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:735X3R0TS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 10 mL
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	5 mg in 10 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	

<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>PROPYL GALLATE</b> (UNII: 8D4SNN7V92)	
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	

### Product Characteristics

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

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0631-1	1 in 1 CARTON	03/30/2023	
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	03/30/2023	

**Labeler** - CARDINAL HEALTH 110, LLC. DBA LEADER (063997360)

### Establishment

Name	Address	ID/FEI	Business Operations
Guardian Drug Company		119210276	MANUFACTURE(70000-0631)

Revised: 3/2023

CARDINAL HEALTH 110, LLC. DBA LEADER