

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

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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)**

**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

**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)

◀ **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:  
Stuffy Nose,  
Runny Nose,  
Sneezing,  
Cough

Alcohol-Free

100% Money  
Back Guarantee

**4 FL OZ (118 mL)**

**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.

**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

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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.** MFR# 53041

DIST. BY CAH DUBLIN, OH 43017  
www.myleader.com 1-800-200-6313  
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**CIN 5820006 REV. 1/23 EXP:**



CHILDRENS COLD AND COUGH			
brompheniramine maleate, dextromethorphan, phenylephrine hcl liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0631
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
<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 Drug	M012	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: 12/2024

CARDINAL HEALTH 110, LLC. DBA LEADER