

**CHILDRENS DIBROMM COLD AND ALLERGY- brompheniramine maleate, phenylephrine hcl liquid
Cardinal Health (Leader) 70000**

Drug Facts

Active ingredients (in each 10 mL)

Brompheniramine maleate 2 mg

Phenylephrine HCl 5 mg

Purposes

Antihistamine

Nasal decongestant

Uses

- temporarily relieves 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

- 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
- high blood pressure
- thyroid disease
- diabetes
- glaucoma
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis

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 use more than directed**
- drowsiness may occur
- avoid alcoholic beverages
- alcohol, sedatives, and tranquilizers may increase drowsiness
- 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 get better within 7 days or are accompanied by fever

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 use any other dosing device.
- keep dosing cup with product
- mL = milliliter

age	dose
adults and children 12 years and over	20 mL every 4 hours
children 6 to 11 years	10 mL every 4 hours
children under 6 years	do not use

Other information

- **each 10 mL contains:** sodium 6 mg
- store between 20-25°C (68-77°F). Do not refrigerate.

Inactive ingredients

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

Questions or comments?

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

Principal Display Panel

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

Children Cold & Allergy

Brompheniramine Maleate, 2 mg

Phenylephrine HCl, 5 mg

Antihistamine

Nasal Decongestant

Grape Flavor

Alcohol-Free

For Ages 6 Years & Over

Relieves

Itchy, Watery Eyes

Runny Nose

Sneezing

Stuffy Nose

Itching of the Nose or Throat

FL OZ (mL)

Dosing Cup Included

*This product is not manufactured or distributed by Pfizer Consumer Healthcare, distributors of Children's Dimetapp® Cold & Allergy.

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

DISTRIBUTED BY CARDINAL HEALTH

DUBLIN, OHIO 43017

www.myleader.com

Package Label

[Redacted]

LEADER Children's Cold & Allergy Grape Flavor

[Redacted]

LEADER Children's Cold & Allergy Grape Flavor

CHILDRENS DIBROMM COLD AND ALLERGY

brompheniramine maleate, phenylephrine hcl liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0057
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BROMPHENIRAMINE MALEATE (UNII: IXA7C9ZN03) (BROMPHENIRAMINE - UNII:H57G17P2FN)	BROMPHENIRAMINE MALEATE	2 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)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0057-1	1 in 1 BOX	04/30/2020	
1		118 mL in 1 BOTTLE, PLASTIC; 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	04/30/2020	

Labeler - Cardinal Health (Leader) 70000 (063997360)

Revised: 2/2024

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