

**COLD AND COUGH CHILDRENS- brompheniramine maleate, dextromethorphan hbr, phenylephrine hcl liquid  
QUALITY CHOICE (Chain Drug Marketing Association)**

*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.*

-----  
**Drug Facts**

**Active ingredients (in each 10 mL)**

Brompheniramine Maleate 2 mg

Dextromethorphan HBr 10 mg

Phenylephrine HCl 5 mg

**Purposes**

Antihistamine

Cough suppressant

Nasal decongestant

**Uses**

- temporarily 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
  - sneezing
  - itchy, watery eyes
  - 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

- thyroid disease
- diabetes
- glaucoma
- high blood pressure
- trouble urinating 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 use more than directed**
- marked 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 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 a sign of a serious condition

**If pregnant or breast-feeding,**

ask a health professional before use.

**Keep out of reach of children.**

**Overdose warning:** 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 5 mg
- store between 20-25°C (68-77°F). Do not refrigerate.

## **Inactive ingredients**

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

## **Principal Display Panel**

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

### **Children's Dibromm**

#### **Cold & Cough**

Brompheniramine Maleate Antihistamine

Dextromethorphan HBr Cough Suppressant

Phenylephrine HCl Nasal Decongestant

For Ages 6 & Over

Alcohol Free

Grape Flavor

FL OZ (mL)

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® Cold & Cough.

Distributed by C.D.M.A., Inc. ©

43157 W. Nine Mile

Novi, MI 48376-0995

[www.qualitychoice.com](http://www.qualitychoice.com)

Question: 248-449-9300

## **Product Label**

**Drug Facts (continued)**

**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 5 mg
- store between 20-25°C (68-77°F). Do not refrigerate.

**Inactive ingredients** 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 1-248-448-9300 Monday-Friday 9AM-5PM EST

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

**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 C.D.M.A., Inc.®  
43157 W. Nine Mile  
Novi, MI 48375  
www.qualitychoice.com  
Questions: 248-449-9300



NDC 63868-775-04

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

# Children's Dibromm

**Cold & Cough**

Brompheniramine Maleate  
Antihistamine  
Dextromethorphan HBr  
Cough Suppressant  
Phenylephrine HCl  
Nasal Decongestant

For Ages 6 & Over  
Alcohol-Free

**Grape Flavor**



**4 FL OZ (118 mL)**



NDC 63868-775-04

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

# Children's Dibromm

**Cold & Cough**

Brompheniramine Maleate  
Antihistamine  
Dextromethorphan HBr  
Cough Suppressant  
Phenylephrine HCl  
Nasal Decongestant

For Ages 6 & Over  
Alcohol-Free

**Grape Flavor**



**4 FL OZ (118 mL)**



PLD-F261D FC004151

Lot No.:  
Exp. Date:

## Drug Facts

**Active ingredients (in each 10 mL)**

Brompheniramine maleate 2 mg	Antihistamine
Dextromethorphan HBr 10 mg	Cough suppressant
Phenylephrine HCl 5 mg	Nasal decongestant

### Uses

- temporarily 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
  - sneezing
  - itchy, watery eyes
  - 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
- thyroid disease
- trouble urinating 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 use more than directed
- marked 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 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.**

## QUALITY CHOICE Children's Dibromm Cold & Cough

## COLD AND COUGH CHILDRENS

brompheniramine maleate, dextromethorphan hbr, phenylephrine hcl liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63868-775
<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:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 10 mL

<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	<b>PHENYLEPHRINE HYDROCHLORIDE</b>	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>TRISODIUM CITRATE DIHYDRATE</b> (UNII: B22547B95K)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	

### Product Characteristics

<b>Color</b>		<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:63868-775-04	1 in 1 BOX	09/30/2015	09/30/2025
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 final	part341	09/30/2015	09/30/2025

**Labeler** - QUALITY CHOICE (Chain Drug Marketing Association) (011920774)

Revised: 5/2023

QUALITY CHOICE (Chain Drug Marketing Association)