# CHILDRENS COLD AND COUGH RELIEF- brompheniramine maleate, dextromethorphan hbr, phenylephrine hcl liquid Family Dollar (FAMILY WELLNESS)

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 (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

- 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 persistent or chronic cough that lasts such 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 occurs
- 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 a 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 1-877-753-3935 Monday-Friday 9AM-5PM EST

# **Principal Display Panel**

COMPARE TO THE ACTIVE INGREDIENTS IN CHILDREN'S DIMETAPP® COLD & COUGH\* Children's

# **Cold & Cough Relief**

Brompheniramine maleate Antihistamine

Dextromethorphan HBr Cough Suppressant

Phenylephrine HCl Nasal Decongestant

Relieves Nasal Symptoms:

- Stuffy nose
- Runny nose
- Sneezing

# Plus Other Symptoms:

- Itchy, watery eyes
- Cough
- Itching of the nose or throat

Alcohol free

**GRAPE FLAVOR** 

FL OZ (mL)

Dosing Cup Included

\*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:** 

MIDWOOD BRANDS, LLC

# Package Label



#### FAMILY WELLNESS Children's Cold & Cough Relief

PLD-G261D FC006023

#### CHILDRENS COLD AND COUGH RELIEF

brompheniramine maleate, dextromethorphan hbr, phenylephrine hcl liquid

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:55319-313

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

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

F	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:55319- 313-04	1 in 1 BOX	10/31/2015	10/31/2025	
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	10/31/2015	10/31/2025	

# Labeler - Family Dollar (FAMILY WELLNESS) (024472631)

Revised: 1/2023 Family Dollar (FAMILY WELLNESS)