

**CHILDRENS DIMETAPP COLD AND COUGH- brompheniramine maleate,
dextromethorphan hbr, phenylephrine hcl liquid
FAMILY DOLLAR SERVICES INC**

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.

Children's Cold & Cough 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:
 - Nasal congestion
 - runny nose
 - cough
 - sneezing
 - itchy, watery eyes due to hay fever
 - 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
- trouble urinating due to an enlarged prostate gland
- glaucoma
- 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**
- may cause marked drowsiness
- 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 get better within 7 days or are 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 right away at 1-800-222-1222.

Directions

- do not take more than 6 doses in any 24-hour period
- measure only with dosage cup provided
- keep dosage cup with product
- ml = milliliter

age	dose
adults and children 12 years and 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 6 mg**
- store at room temperature.

Inactive ingredients

anhydrous citric acid, FD&C blue no. 1, FD&C red no. 40, artificial flavor, glycerin, propylene glycol, propyl gallate, purified water, sodium benzoate, sodium citrate, sorbitol solution, sucralose

Questions or comments?

1-866-467-2748

PRINCIPAL DISPLAY PANEL

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

NDC 55319-645-04

Children's

Cold & Cough

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**

For Ages 6 Years and Over

Grape Flavor

Naturally and Artificially Flavored

4 FL OZ (118 ml)

Distributed by:

This product is not distributed by Foundation Consumer Brands, LLC, the distributor of Children's Dimetapp® Cold & Cough.

TAMPER EVIDENT: DO NOT USE IF PRINTED INNER SEAL UNDER CAP IS TORN OR MISSING

Drug Facts

Active ingredients (in each 10 mL) Purposes
 Brompheniramine Maleate, 2 mg.....Antihistamine
 Dextromethorphan HBr, 10 mg.....Cough Suppressant
 Phenylephrine HCl, 5 mg.....Nasal Decongestant

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When using this product

- do not use more than directed
- may cause marked drowsiness
- avoid alcoholic beverages
- alcohol, sedatives and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- irritability may occur, especially in children

Stop use and ask a doctor if

- new-onset, dizziness or sleeplessness occurs
- symptoms do not get better 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.

Drug Facts (continued)

If pregnant or breast-feeding, ask a health professional before use.

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Inactive ingredients citric acid, FD&C Blue No. 1, FD&C Red No. 40, flavors, glycerin, propylene glycol, propyl galate, purified water, sodium benzoate, sodium citrate, sorbitol liquid, sucralose.

Questions or comments? 1-866-467-2748

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IMPORTANT:
Keep this capon for future reference on full labeling.

DISTRIBUTED BY: MIDWOOD BRANDS, LLC
300 WOLVO PKWY, CHESAPEAKE, VA 23020 USA

NOT 100% SATISFIED?
Return within 30 days to any Family Dollar store for a refund (with receipt) or exchange.

FAMILY Wellness

children's
COLD & COUGH

FOR AGES 6 & OVER

Relieves Nasal Symptoms

- Stuffy Nose
- Runny Nose
- Sneezing

Plus Other Symptoms

- Itchy, Watery Eyes
- Cough

GRAPE FLAVOR
NATURALLY AND ARTIFICIALLY FLAVORED

NDC 55319-645-04

4 FL OZ (118 mL)

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NATURALLY AND ARTIFICIALLY FLAVORED

NDC 55319-645-04

4 FL OZ (118 mL)

SKU 997586 84504FDFC

0 32251 92617 4

Lot:

Exp:

CHILDRENS DIMETAPP COLD AND COUGH

brompheniramine maleate, dextromethorphan hbr, phenylephrine hcl liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55319-645
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
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RT19KYH) (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)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color	PURPLE (purple liquid)	Score	
Shape		Size	
Flavor	GRAPE (grape flavor and odor)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55319-645-04	1 in 1 CARTON	05/08/2023	
1		118 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	05/08/2023	

Labeler - FAMILY DOLLAR SERVICES INC (024472631)

Revised: 9/2023

FAMILY DOLLAR SERVICES INC