

DIMETAPP COLD AND COUGH- brompheniramine maleate, dextromethorphan hydrobromide, and phenylephrine hydrochloride elixir
Foundation Consumer Brands

Dimetapp[®]
Cold and Cough

Drug Facts

<i>Active ingredients (in each 10 mL)</i>	<i>Purposes</i>
Brompheniramine maleate, 2 mg	Antihistamine
Dextromethorphan HBr, 10 mg	Cough suppressant
Phenylephrine HCl, 5 mg	Nasal decongestant

Uses

- temporarily relieves:
 - nasal congestion
 - runny nose
 - cough
 - sneezing
 - itching of the nose or throat
 - itchy, watery eyes due to hay fever
- 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 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
- 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 right away.

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 20-25°C (68-77°F)

Inactive ingredients

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

sucralose

Questions or comments?

Call **1-888-594-0828** weekdays 9 AM to 5 PM EST

Distributed by:
Foundation Consumer Brands, LLC
Pittsburgh, PA 15212

PRINCIPAL DISPLAY PANEL - 118 mL Bottle Carton

CHILDREN'S
Dimetapp[®]

BROMPHENIRAMINE MALEATE (Antihistamine)
DEXTROMETHORPHAN HBr (Cough Suppressant)
PHENYLEPHRINE HCl (Nasal Decongestant)

PHARMACIST
RECOMMENDED

Cold &
Cough

Relieves + comforts:

- Stuffy, runny nose
- Itchy, watery eyes
- Sneezing
- Cough

6+
YRS

4 FL OZ
(118 mL)

Grape Flavor • Alcohol Free



DIMETAPP COLD AND COUGH

brompheniramine maleate, dextromethorphan hydrobromide, and phenylephrine hydrochloride elixir

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80070-310
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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BROMPHENIRAMINE MALEATE (UNII: IXA7C9ZN03) (BROMPHENIRAMINE - UNII:H57G17P2FN)	BROMPHENIRAMINE MALEATE	1 mg in 5 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	5 mg in 5 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1VS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 5 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: 059QF0K00R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color	purple	Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80070-310-04	1 in 1 CARTON	09/15/2021	12/31/2026
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:80070-310-08	1 in 1 CARTON	09/15/2021	12/31/2026
2		237 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	09/15/2021	12/31/2026

Labeler - Foundation Consumer Brands (117603632)

