

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

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.

Dimetapp®
Cold and Cough

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

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	
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:80070-310-08	1 in 1 CARTON	09/15/2021	
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 FINAL	part341	09/15/2021	

Labeler - Foundation Consumer Brands (117603632)

