

CHILDRENS DIMETAPP MULTI-SYMPTOM COLD RELIEF DYE-FREE- brompheniramine maleate, dextromethorphan hbr, phenylephrine hcl solution
Richmond Division of Wyeth

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 Dimetapp® Multi-Symptom Cold Relief Dye-Free

Drug Facts

Active ingredients (in each 10 ml)	Purposes
Brompheniramine maleate, USP 2 mg	Antihistamine
Dextromethorphan HBr, USP 10 mg	Cough suppressant
Phenylephrine HCl, USP 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
- 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

- you get nervous, dizzy, or sleepless
- 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, glycerin, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol solution, sucralose.

Questions or comments?

Call weekdays from 9 AM to 5 PM EST at **1-800-762-4675**

For most recent product information, visit www.dimetapp.com

Distributed by: Pfizer, Madison, NJ 07940 USA

PRINCIPAL DISPLAY PANEL - 118 ml Bottle Label

**Children's
Dimetapp®**

Multi-Symptom Cold Relief

DYE-FREE

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

4 FL OZ (118 ml)

Active ingredients (in each 10 ml): Brompheniramine maleate, USP 2 mg; Dextromethorphan HBr, USP 10 mg; Phenylephrine HCl, USP 5 mg

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.

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Packaged with Tamper-Evident bottle cap. Do Not Use if breakable ring is separated or missing.

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Alcohol-free
Distributed by: Pfizer
Madison, NJ 07940 USA
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visit www.dimetapp.com

LOT:
EXP:

PAA070508

PRINCIPAL DISPLAY PANEL - 118 ml Bottle Carton

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For Ages

6 Yrs.

& Over

4 FL OZ (118 ml) alcohol-free • grape flavor

**Children's
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**Multi-Symptom
Cold Relief**

DYE-FREE

For most recent product information, visit
www.dimetapp.com

We pledge to you that Dimetapp® products
contain only high quality ingredients
and meet strict standards of quality and safety.
You can trust Dimetapp® products for your family.

Dosage Cup Provided

Should be 18 or older to purchase

PARENTS:
Learn about teen medicine abuse

www.StopMedicineAbuse.org

Distributed by: Pfizer, Madison, NJ 07940 USA
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Drug Facts (continued)

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6 Yrs.
& Over**

4 FL OZ (118 ml) alcohol-free • grape flavor

PAA105601

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brompheniramine maleate, dextromethorphan hbr, phenylephrine hcl solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0031-2295
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: 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)	
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	YELLOW (colorless to pale yellow, clear liquid)	Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0031-2295-12	1 in 1 CARTON	06/01/2016	
1		118 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	06/01/2016	

