

**DIMAPHEN DM- brompheniramine maleate, dextromethorphan hbr, phenylephrine hcl solution**  
**Major Pharmaceuticals**

*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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**Major Pharmaceuticals Children's Dimaphen DM Drug Facts**

**Active ingredients (in each 10 mL)**

Brompheniramine maleate, USP 2 mg

Dextromethorphan HBr, USP 10 mg

Phenylephrine HCl, USP 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**

- 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.
- to make a child sleepy

**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 such as emphysema or chronic bronchitis
- cough that lasts or is chronic such as occurs with smoking, asthma or emphysema

**Ask a doctor or pharmacist before use if you are**

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 for more than 7 days, comes back, or is accompanied by fever, rash, or persistent headache. A persistent cough may be a sign 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 (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 4 mg
- store at 20°-25°C (68°-77°F)

**Inactive ingredients**

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

**Questions or comments?**

**1-800-616-2471**

**Principal Display Panel**

Children's

Dimaphen™ DM

ANTI-HISTAMINE, Brompheniramine Maleate

COUGH SUPPRESSANT, Dextromethorphan HBr

NASAL DECONGESTANT, Phenylephrine HCl

Relieves – Nasal Symptoms

Stuffy Nose – Runny Nose

Sneezing

Plus Other Symptoms

Itchy, Watery Eyes

Cough

GRAPE FLAVOR

Alcohol-Free

6 yrs. and older

COMPARE TO the active ingredients of DIMETAPP® COLD & COUGH

4 FL. OZ. (118 mL.)



## DIMAPHEN DM

brompheniramine maleate, dextromethorphan hbr, phenylephrine hcl solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0904-6463
<b>Route of Administration</b>	ORAL		

**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
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 10 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SORBITOL</b> (UNII: 506T60A25R)	

**Product Characteristics**

<b>Color</b>	PURPLE (Clear bluish-red)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	GRAPE	<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-6463-20	1 in 1 CARTON	09/11/2006	
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	09/11/2006	

**Labeler** - Major Pharmaceuticals (191427277)