

## **CHILDRENS COLD AND ALLERGY- brompheniramine maleate, phenylephrine hcl elixir Select Brand Dist.**

*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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### **Drug Facts**

#### **Active ingredients (in each 5 mL, 1 teaspoon)**

Brompheniramine maleate, USP 1 mg

Phenylephrine HCl, USP 2.5 mg

### **Purpose**

Antihistamine

Nasal decongestant

### **Uses**

- temporarily relieves 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
- glaucoma
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis

#### **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

**If pregnant or breast-feeding,**

ask a health professional before use.

**Keep this and all drugs out of the reach of children.**

In case of accidental overdose, seek professional assistance or contact a Poison Control Center (1-800-222-1222) immediately.

**Directions**

- do not take more than 6 doses in a 24-hour period
- use enclosed dosage cup
- tsp = teaspoon, mL = milliliter

age	dose
adults and children 12 years and over	4 teaspoons (20 mL) every 4 hours
children 6 to under 12 years	2 teaspoons (10 mL) every 4 hours
children under 6 years	do not use

**Other information**

- **each teaspoon contains:** sodium 3 mg
- store at room temperature

**Inactive ingredients**

blue #1, citric acid, flavor, glycerin, propylene glycol, purified water, red 40, sodium benzoate, sodium citrate, sorbitol, sucralose

**Principal Display Panel****Children's Cold & Allergy Elixir**

RELIEVES:

Stuffy Nose; Itchy, Watery Eyes; Runny Nose; Sneezing

Brompheniramine Maleate - Antihistamine

Phenylephrine HCl - Nasal Decongestant

\*Compare to the Active Ingredients of DIMETAPP® Elixir

Grape Flavor

Alcohol Free

FL OZ (mL)

**TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL ON THE BOTTLE IS BROKEN OR MISSING.**

\*This product is not manufactured or distributed by Wyeth Consumer Healthcare, distributors of Dimetapp®.

DISTRIBUTED BY: SELECT BRAND® DISTRIBUTORS

Pine Bluff, AR 71603 USA

AC (870) 535-3635

MADE IN THE USA

**Package Label**

<p><b>Drug Facts</b> (continued)</p> <p><b>Ask a doctor or pharmacist before use if you are</b></p> <ul style="list-style-type: none"> <li>taking any other oral nasal decongestant or stimulant</li> <li>taking sedatives or tranquilizers</li> </ul> <p><b>When using this product</b></p> <ul style="list-style-type: none"> <li>do not use more than directed</li> <li>may cause marked drowsiness • avoid alcoholic beverages • alcohol, sedatives, and tranquilizers may increase drowsiness • be careful when driving a motor vehicle or operating machinery</li> <li>excitability may occur, especially in children</li> </ul> <p><b>Stop use and ask a doctor if</b></p> <ul style="list-style-type: none"> <li>you get nervous, dizzy or sleepless</li> <li>symptoms do not get better within 7 days or are accompanied by fever</li> </ul> <p><b>If pregnant or breast-feeding,</b> ask a health professional before use.</p> <p><b>Keep this and all drugs out of the reach of children.</b> In case of accidental overdose, seek professional assistance or contact a Poison Control Center (1-800-222-1222) immediately.</p> <p><b>Directions</b> • do not take more than 6 doses in a 24-hour period • use enclosed dosage cup</p> <ul style="list-style-type: none"> <li>tsp = teaspoon, mL = milliliter</li> </ul> <table border="1"> <thead> <tr> <th>age</th> <th>dose</th> </tr> </thead> <tbody> <tr> <td>adults and children 12 years and over</td> <td>4 teaspoons (20 mL) every 4 hours</td> </tr> <tr> <td>children 6 to under 12 years</td> <td>2 teaspoons (10 mL) every 4 hours</td> </tr> <tr> <td>children under 6 years</td> <td>do not use</td> </tr> </tbody> </table> <p><b>Other information</b></p> <ul style="list-style-type: none"> <li>each teaspoon contains: sodium 3 mg</li> <li>store at room temperature</li> </ul> <p><b>Inactive ingredients</b> blue 1, citric acid, flavor, glycerin, propylene glycol, purified water, red 40, sodium benzoate, sodium citrate, sorbitol, sucralose</p>	age	dose	adults and children 12 years and over	4 teaspoons (20 mL) every 4 hours	children 6 to under 12 years	2 teaspoons (10 mL) every 4 hours	children under 6 years	do not use	<p>NDC 15127-954-04</p> <p><b>select brand</b> the lower price name brand</p> <p><b>CHILDREN'S COLD &amp; ALLERGY Elixir</b></p> <p><b>RELIEVES:</b> Stuffy Nose, Itchy, Watery Eyes, Runny Nose, Sneezing</p> <p>BROMPHENIRAMINE MALEATE - ANTIHISTAMINE PHENYLEPHRINE HCl - NASAL DECONGESTANT</p> <p><b>*Compare to the Active Ingredients of DIMETAPP® Elixir</b></p> <p><b>GRAPE FLAVOR</b></p> <p><b>ALCOHOL FREE 4 FL OZ (118 mL)</b></p>	<p>NDC 15127-954-04</p> <p><b>select brand</b> the lower price name brand</p> <p><b>CHILDREN'S COLD &amp; ALLERGY Elixir</b></p> <p><b>RELIEVES:</b> Stuffy Nose, Itchy, Watery Eyes, Runny Nose, Sneezing</p> <p>BROMPHENIRAMINE MALEATE - ANTIHISTAMINE PHENYLEPHRINE HCl - NASAL DECONGESTANT</p> <p><b>*Compare to the Active Ingredients of DIMETAPP® Elixir</b></p> <p><b>GRAPE FLAVOR</b></p> <p><b>ALCOHOL FREE 4 FL OZ (118 mL)</b></p>	<p><b>Drug Facts</b></p> <table border="1"> <thead> <tr> <th>Active ingredients (in each 5 mL, 1 teaspoon)</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Brompheniramine maleate, USP 1 mg.....</td> <td>Antihistamine</td> </tr> <tr> <td>Phenylephrine HCl, USP 2.5 mg.....</td> <td>Nasal decongestant</td> </tr> </tbody> </table> <p><b>Uses</b></p> <ul style="list-style-type: none"> <li>temporarily relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies</li> <li>temporarily relieves these symptoms due to hay fever (allergic rhinitis): • runny nose • sneezing • itchy, watery eyes • itching of the nose or throat</li> <li>temporarily restores freer breathing through the nose</li> </ul> <p><b>Warnings</b></p> <p><b>Do not use</b></p> <ul style="list-style-type: none"> <li>to sedate a child or to make a child sleepy</li> <li>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.</li> </ul> <p><b>Ask a doctor before use if you have</b></p> <ul style="list-style-type: none"> <li>heart disease • high blood pressure</li> <li>thyroid disease • diabetes • glaucoma</li> <li>trouble urinating due to an enlarged prostate gland</li> <li>a breathing problem such as emphysema or chronic bronchitis</li> </ul> <p><small>*This product is not manufactured or distributed by Wyeth Consumer Healthcare, distributors of Dimetapp®.</small></p> <p>Distributed by: <b>SELECT BRAND® DISTRIBUTORS</b> Pine Bluff, AR 71603 USA AC (870) 535-3635 <b>MADE IN THE USA</b></p>	Active ingredients (in each 5 mL, 1 teaspoon)	Purpose	Brompheniramine maleate, USP 1 mg.....	Antihistamine	Phenylephrine HCl, USP 2.5 mg.....	Nasal decongestant
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Select Brand Children's Cold & Allergy Grape Elixir

**CHILDRENS COLD AND ALLERGY**

brompheniramine maleate, phenylephrine hcl elixir

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:15127-954
Route of Administration	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BROMPHENIRAMINE MALEATE (UNII: IXA7C9ZN03) (BROMPHENIRAMINE - UNII:H57G17P2FN)	BROMPHENIRAMINE MALEATE	1 mg in 5 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	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)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

## Product Characteristics

Color		Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:15127-954-04	1 in 1 BOX		
1		118 mL in 1 BOTTLE, PLASTIC; 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	07/11/2011	

