

**CHILDRENS DIBROMM COLD AND COUGH- brompheniramine maleate,
dextromethorphan hbr, phenylephrine hcl liquid
Fred's Inc**

Drug Facts

Active ingredients (in each 10 mL)

Brompheniramine maleate 2 mg

Dextromethorphan HBr 10 mg

Phenylephrine HCl 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

- 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
- 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**
- marked drowsiness may occur
- 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 occur
- symptoms do not improve 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 (1-800-222-1222) right away.

Directions

- do not take more than 6 doses in any 24-hour period
- measure only with dosing cup provided. Do not use any other dosing device
- keep dosing cup with product
- mL=milliliter

age	dose
adults and children 12 years and over	20 mL every 4 hours
children 6 to 11 years	10 mL every 4 hours
children under 6 years	do not use

Other information

- **each 10 mL contains: sodium 5 mg**

- store at 20-25°C (68-77°F). Do not refrigerate.

Inactive ingredients

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

Questions or Comments?

Call **1-877-753-3935 Monday-Friday 9AM-5PM EST**

Principal Display Panel

6 + YEARS

CHILDREN'S

COLD & COUGH

BROMPHENIRAMINE MALEATE 2mg

Antihistamine

DEXTROMETHORPHAN HBr 10mg

Cough Suppressant

PHENYLEPHRINE HCl 5mg

Nasal Decongestant

Relieves:

- Cough
- Itchy, Watery Eyes
- Runny Nose
- Sneezing
- Stuffy Nose
- Itchy Nose or Throat

GRAPE FLAVOR

Alcohol Free

FL OZ (mL)

Dosing Cup Included

*Compare To Active Ingredients in Children's Dimetapp® Cold & Cough

*This product is not manufactured or distributed by Pfizer Consumer Healthcare, distributors of Children's Dimetapp® Cold & Cough.

TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF PRINTED SAFETY SEAL AROUND BOTTLE OR UNDER CAP IS BROKEN OR MISSING.

DISTRIBUTED BY: fred's inc.

4300 NEW GETWELL RD, MEMPHIS TN, 38118

www.fredsinc.com

Package Label

<p>Drug Facts (continued)</p> <p>Directions</p> <ul style="list-style-type: none"> do not take more than 6 doses in any 24-hour period measure only with dosing cup provided. Do not use any other dosing device. keep dosing cup with product mL = milliliter <table border="1"> <tr> <th>Age</th> <th>Dose</th> </tr> <tr> <td>adults and children 12 years and over</td> <td>20 mL every 4 hours</td> </tr> <tr> <td>children 6 to 11 years</td> <td>10 mL every 4 hours</td> </tr> <tr> <td>children under 6 years</td> <td>do not use</td> </tr> </table> <p>Other information</p> <ul style="list-style-type: none"> each 10 mL contains: sodium 5 mg store between 20-25°C (68-77°F). Do not refrigerate. <p>Inactive ingredients citric acid, FD&C blue #1, FD&C red #40, flavor, glycerin, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol, sucralose</p> <p>Questions or comments? Call 1-877-753-3936 Monday-Friday 9AM-5PM EST</p>	Age	Dose	adults and children 12 years and over	20 mL every 4 hours	children 6 to 11 years	10 mL every 4 hours	children under 6 years	do not use	<p style="text-align: right;">NDC 55315-313-04</p>  <p style="text-align: center;">6+ YEARS</p> <h2 style="text-align: center;">CHILDREN'S COLD & COUGH</h2> <p>BROMPHENIRAMINE MALEATE 2mg Antihistamine DEXTROMETHORPHAN HBr 10mg Cough Suppressant PHENYLEPHRINE HCl 5mg Nasal Decongestant</p> <p>Relieves:</p> <ul style="list-style-type: none"> Cough Itchy, Watery Eyes Runny Nose Sneezing Stuffy Nose Itchy Nose or Throat  <p>GRAPE FLAVOR Alcohol Free</p> <p>4 FL OZ (118 mL)</p> <p><small>*Compare To Active Ingredients in Children's Dimetapp® Cold & Cough</small></p>	<p style="text-align: right;">NDC 55315-313-04</p>  <p style="text-align: center;">6+ YEARS</p> <h2 style="text-align: center;">CHILDREN'S COLD & COUGH</h2> <p>BROMPHENIRAMINE MALEATE 2mg Antihistamine DEXTROMETHORPHAN HBr 10mg Cough Suppressant PHENYLEPHRINE HCl 5mg Nasal Decongestant</p> <p>Relieves:</p> <ul style="list-style-type: none"> Cough Itchy, Watery Eyes Runny Nose Sneezing Stuffy Nose Itchy Nose or Throat  <p>GRAPE FLAVOR Alcohol Free</p> <p>4 FL OZ (118 mL)</p> <p><small>*Compare To Active Ingredients in Children's Dimetapp® Cold & Cough</small></p>	<p>Drug Facts</p> <table border="1"> <thead> <tr> <th>Active ingredients (in each 10 mL)</th> <th>Purposes</th> </tr> </thead> <tbody> <tr> <td>Brompheniramine maleate 2 mg</td> <td>Antihistamine</td> </tr> <tr> <td>Dextromethorphan HBr 10 mg</td> <td>Cough suppressant</td> </tr> <tr> <td>Phenylephrine HCl 5 mg</td> <td>Nasal decongestant</td> </tr> </tbody> </table> <p>Uses</p> <ul style="list-style-type: none"> 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 itchy, watery eyes sneezing itching of the nose or throat temporarily restores freer breathing through the nose <p>Warnings</p> <p>Do not use</p> <ul style="list-style-type: none"> to sedate a child or to make a child sleep 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. 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CHILDRENS DIBROMM COLD AND COUGH

brompheniramine maleate, dextromethorphan hbr, phenylephrine hcl liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55315-313
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)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
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:55315-313-04	1 in 1 BOX	06/30/2015	06/30/2024
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 Drug	M012	06/30/2015	06/30/2024

Labeler - Freds Inc (005866116)

