

**DIBROMM COLD AND COUGH CHILDRENS- brompheniramine maleate,
dextromethorphan hbr, phenylephrine hcl liquid
P & L Development, LLC**

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.

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 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 occurs
- 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 between 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

Compare to the active ingredients in Children's Dimetapp® Cold & Cough*

Children's dibromm

Cold & Cough

Brompheniramine maleate 2 mg antihistamine

Dextromethorphan HBr 10 mg Cough suppressant

Phenylephrine HCl 5 mg Nasal decongestant

Relieves:

- cough
- itchy, watery eyes
- runny nose
- sneezing
- stuffy nose
- itching of the nose or throat

for ages 6 and over

Alcohol free

FL OZ (mL)

grape flavor

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

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

Manufactured by:

PL Developments

11865 S. Alameda St

Package Label

Drug Facts (continued)

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- do not take more than 6 doses in any 24-hour period
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PARENTS:
Learn about teen medicine abuse
www.StopMedicineAbuse.org



Manufactured by:
PL Developments
11865 S. Alameda St
Lynwood, CA 90262

Compare to the active ingredients in Children's Dimetapp® Cold & Cough*
NDC 49580-0313-4

ready in case

children's dibromm cold & cough

brompheniramine maleate 2 mg antihistamine
dextromethorphan HBr 10 mg cough suppressant
phenylephrine HCl 5 mg nasal decongestant

relieves:

- cough
- runny nose
- stuffy nose
- itching of the nose or throat
- itchy, watery eyes
- sneezing

for ages 6 and over alcohol free

4 fl oz (118 mL) grape flavor

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ReadyinCase Children dibromm Cold & Cough Grape Liquid

DIBROMM COLD AND COUGH CHILDRENS

brompheniramine maleate, dextromethorphan hbr, phenylephrine hcl liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49580-0313
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:49580-0313-4	1 in 1 BOX	05/31/2016	
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	05/31/2016	

Labeler - P & L Development, LLC (101896231)