CHILDRENS DIMETAPP COLD AND ALLERGY- brompheniramine maleate, phenylephrine hcl liquid
GlaxoSmithKline Consumer Healthcare Holdings (US) 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, USP 2 mg

Phenylephrine HCl , USP 5 mg

PURPOSES

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
- trouble urinating due to an enlarged prostate gland
- glaucoma
- a breathing problem such as emphysema, asthma, 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**
- 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

- 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 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, FD&C blue no. 1, FD&C red no. 40, 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**

PRINCIPAL DISPLAY PANEL

NDC 0031-2235-13

Children's
Dimetapp®

BROMPHENIRAMINE MALEATE (Antihistamine)
PHENYLEPHRINE HCl (Nasal Decongestant)

Cold
& **Allergy**

Relieves Nasal Symptoms

- Stuffy Nose
- Runny Nose
- Sneezing

Plus Other Symptoms

- Itchy, Watery Eyes

For Ages
6 Yrs.
& Over

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

CHILDRENS DIMETAPP COLD AND ALLERGY

brompheniramine maleate, phenylephrine hcl liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0031-2235
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: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color	PURPLE (purple liquid)	**Score**	
Shape		**Size**	
Flavor	GRAPE (grape flavor and odor)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0031-2235-13	1 in 1 CARTON	02/07/2007	04/30/2022
1		118 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		
2	NDC:0031-2235-19	1 in 1 CARTON	02/07/2007	04/30/2022
2		237 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	02/07/2007	04/30/2022

Labeler - GlaxoSmithKline Consumer Healthcare Holdings (US) LLC (079944263)

Revised: 6/2021 GlaxoSmithKline Consumer Healthcare Holdings (US) LLC