CHILDRENS COLD AND ALLERGY - brompheniramine maleate and phenylephrine hcl solution
Chain Drug Consortium, 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 5 mL (1 tsp) dose)

Brompheniramine maleate, USP 1 mg
Phenylephrine HCl, USP 2.5 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 (1-800-222-1222) 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
- do not use any other dosing device
- tsp=teaspoon, mL = milliliter

Age	Dose
adults and children 12 years and over	20 mL (4 tsp) every 4 hours
children 6 to under 12 years	10 mL (2 tsp) every 4 hours
children under 6 years	**do not use**

Other information

• **each 5 mL contains:** sodium 2 mg

• store at 20-25ºC (68-77ºF)

• see bottom panel for lot number and expiration date

Inactive ingredients

Anhydrous citric acid, FD&C Blue No.1, FD&C Red No. 40, flavor, glycerin, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol solution, sucralose

Questions or comments?

1-855-274-4122

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

Distributed by:
Chain Drug Consortium, LLC
UPARC, Bldg. A3, Suite 338
1020 William Pitt Way
Pittsburgh, PA 15238
www.chaindrugconsortium.com
MADE IN USA

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 4 FL OZ (118 mL Bottle)

NDC 68016-127-04
***Compare to the active ingredients**
in Children's Dimetapp®

Cold & Allergy

Premier Value®

Children's
Clod & Allergy

Brompheniramine Maleate, USP 1 mg –
Antihistamine
Phenylephrine HCl, USP 2.5 mg –
Nasal Decongestant

Relieves Nasal Symptoms:
- **Stuffy Nose**
- **Runny Nose**
- **Sneezing**

Plus Other Symptoms:
- **Itchy, Watery Eyes**

For Ages
6 years
& Over

Grape Flavor

Dosage Cup Provided

Alcohol Free
4 FL OZ (118 mL)

CHILDRENS COLD AND ALLERGY

brompheniramine maleate and phenylephrine hcl solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68016-127
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)	
GRAPE (UNII: 6X543N684K)	
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	**Score**	
Shape		**Size**	
Flavor	GRAPE	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-127-04	1 in 1 CARTON	06/03/2015	
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	06/03/2015	

Labeler - Chain Drug Consortium, LLC (101668460)

Registrant - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
Aurohealth LLC		078728447	MANUFACTURE(68016-127)