CVS CHILDRENS COLD AND ALLERGY- brompheniramine maleate, phenylephrine hcl liquid CVS PHARMACY, INC.

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.

Children's Dimetapp Cold & Allergy Brompheniramine maleate and Phenylephrine HCI

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 at 1-800-222-1222.

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

| ge Dose | |
|---------------------------------------|---------------------|
| adults and children 12 years and over | 20 ml every 4 hours |
| children 6 to under 12 years | 10 ml every 4 hours |

OTHER INFORMATION

- each 10 ml contains: sodium 6 mg
- store at room temperature

INACTIVE INGREDIENTS

anhydrous citric acid, FD&C Blue No. 1, FD&C Red No. 40, flavor, glycerin, propylene glycol, propyl gallate, purified water, sodium benzoate, sodium citrate, sorbitol liquid, sucralose

Questions or comments?

1-866-467-2748

PRINCIPAL DISPLAY PANEL - 118 ml Bottle Label

Compare to the active ingredients in Children's Dimetapp® Cold & Allergy* NDC# 69842-639-04

Children'sCold & Allergy

Brompheniramine Maleate USP (Antihistamine) Phenylephrine HCl USP (Nasal Decongestant)

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

Alcohol-Free • Sugar Free

Ages 6 Years and Over

Grape Flavor

Naturally and Artificially Flavored

4 FL OZ (118 ml)

IMPORTANT: Keep this carton for future reference on full labeling.

Distributed by:

CVS Pharmacy, Inc.

One CVS Drive, Woonsocket, RI 02895

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CVS.com 1-800-SHOP CVS

V12431

CVS Quality

Money Back Guaranteed

*This product is not manufactured or distributed by Pfizer, the distributor of Children's Dimetapp® Cold & Allergy.



CVS CHILDRENS COLD AND ALLERGY

brompheniramine maleate, phenylephrine hcl liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:69842-639

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 | |
| 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) | | |
| PROPYL GALLATE (UNII: 8D4SNN7V92) | | |
| 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 | Imprint Code | |
| Contains | | | |

| Packaging | | | |
|-------------------------|---|-------------------------|-----------------------|
| # Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 NDC:69842-639- | 1 in 1 CARTON | 03/30/2020 | |
| 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 | 03/30/2020 | |
| | | | |

Labeler - cvs Pharmacy, Inc. (062312574)

Revised: 9/2023 CVS PHARMACY, INC.