### CHILDRENS COLD AND COUGH - brompheniramine maleate, dextromethorphan, phenylephrine hcl liquid CVS

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#### Childrens Cold and Cough 577

### ACTIVE INGRADIENTS (in each 10 mL)

Brompheniramine maleate, USP 2 mg Dextromethorphan HBr, USP 10 mg Phenylephrine HCl, USP 5 mg

### PURPOSES

Antihistamine

Cough Suppressant

Nasal decongestant

#### USES

- temporarily relieves cough due to minor bronchial irritation as may occur 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):
- sneezing
- Itching of the nose or throat
- runny nose
- itchy, watery eyes
- temporarily restores freer breathing through the nose

#### WARNINGS

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#### 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, or psychiatric, 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
- glaucoma
- diabetes
- thyroid disease
- high blood pressure
- difficulty in urination 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 sedative or tranquilizers

### WHEN USING THIS PRODUCT

- do not take more than directed
- may cause drowsiness
- alcohol, sedatives, and tranquillizers may increase drowsiness
- avoid alcoholic beverages
- 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 right away.

### DIRECTIONS

- do not take more than 6 doses in any 24-hour period
- measure only with dosing cup provided
- do not exceed recommended dosage
- mL = milliliter

| Age                    | Dose          |
|------------------------|---------------|
| adults & children      | 20 mL         |
| 12 years & over        | every 4 hours |
| children 6 to under    | 10 mL         |
| 12 years               | every 4 hours |
| children under 6 years | do not use    |

### **OTHER INFORMATION**

- each 10 mL contains: sodium 10 mg
- store at 20-25°C (68-77°F)
- measuring cup provided

## **INACTIVE INGREDIENTS**

anhydrous citric acid, artificial flavor, FD&C blue #1, FD&C Red #40, glycerin, propylene glycol, propyl gallate, purified water, sodium benzoate, sodium citrate, sorbitol, sucralose

## PRINCIPAL DISPLAY PANEL

cvs

## Health ®

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

NDC 51316-578-03

Children's

## Cold & Cough

BROMPHENIRAMIINE MALEATE

Antihistamine

DEXTROMETHORPHAN HYDROBROMIDE

Cough Suppressant

PHENYLEPHRINE HYDROCHLORIDE

Nasal Decongestant

DM Liquid

- Relieves nasal congestion; Stuffy nose; Runny nose; Sneezes
- Soothes Cough
- Calm allergy symptoms

Alcohol free

6+ Years

## **Grape Flavor**

Dosage Cup Included

## 4 FL OZ (118 mL)

#### Drug Facts

Active ingredients (in each 10 mL) Purposes Active ingrements for court of many and a second suppressent Brompheniramine maleate, USP 2 mg....Antihistamine Dextromethorphan HBr, USP 10 mg...Cough suppressant Phenylephrine HCI, USP 5 mg......Nasal decongestant

#### Uses

- temporarily relieves cough due to minor bronchial irritation as may occur 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 rhinits): sneezing "tohing of the nose of throat " runny nose" itchy watery eves
   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 codase 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 glaucoma diabetes
   thyroid disease high blood pressure
   difficulty in urination 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 a do not take more than directed
- may cause drowsiness
   alcohol, sedatives, and tranguilizers may increase drowsiness avoid alcoholic beverages
- be careful when driving a motor vehicle or operating machinery

#### Drug Facts (continued)

- 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 right away.

#### Directions

 do not take more than 6 doses in any 24-hour period do not exceed recommended dosage

| Age                    | Dose          |
|------------------------|---------------|
| adults & children      | 20 mL         |
| 12 years & over        | every 4 hours |
| children 6 to under    | 10 mL         |
| 12 years               | every 4 hours |
| children under 6 years | do not use    |

#### Other information

 each 10 mL contains: sodium 10 mg
 store at 20-25°C (68-77°F) measuring cup provided

Inactive ingredients anhydrous citric acid, artificial flavor, FD&C blue #1, FD&C red #40, glycerin, propylene glycol, propyl gallate, purified water, sodium benzoate, sodium citrate, sorbitol, sucralose

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

**KEEP THIS BOX FOR COMPLETE INSTRUCTIONS** 

DO NOT USE IF SEAL UNDER CAP IMPRINTED WITH "SEALED FOR YOUR PROTECTION" IS BROKEN OR MISSING

10 WestRock 1400735-1 12/24

# Children's Cold & Cough

### **DM Liquid**

VCVS Health.

♥CVS Health.

Children's Cold & Cough

Compare to the

active ingredients in Children's Dimetapp\* Cold & Cough\*

BROMPHENIRAMINE MALEATE Antihistamine DEXTROMETHORPHAN HBr Cough suppres PHENYLEPHRINE HCI

#### DM Liquid

- Relieves nasal congestion; Stuffy nose; Runny nose; Sneezes
- Soothes cough
- Calms allergy symptoms





Grape Flavor Dosage Cup Included

## 4 FL OZ (118 mL)

MFR# 53041 **REV 0623** #477080

♥CVS Health.

CVS Health® Children's Cold & Cough offers relief from nasal congestion, runny nose, coughing, and sneezing to help your child get through the day.

# PARENTS:

www.StopMedicineAbuse.org

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LOT:

EXP:



Package

Contains One Bottle

| Drug Facts         Description           Imprinted with "sealed For Your Protection" is Broken or Missing.           Active ingredients (in each 10 mL)         Purposes           Brompheniramine maleate, USP 2 mgAntihistamine           Dextromethorphan HBr, USP 10 mgCough suppressant | ♦ CVS<br>Health. Children's   | <b>Drug Facts</b> (continued)<br>disease), or for 2 weeks after stopping the MAOI drug. If you<br>do not know if your prescription drug contains an MAOI,<br>ask a doctor or pharmacist before taking this product.                              |
|--|---|--|
| Phenylephrine HCl, USP 5 mgNasal decongestant<br><b>Uses</b> temporarily relieves cough due to<br>minor bronchial irritation as may occur with<br>a cold, and nasal congestion due to the  | Cold &<br>Cough   | Directions ■ do not take more than 6 doses in any<br>24-hour period ■ do not exceed recommended dosage<br>■ mL = milliliter  |
| common cold, hay fever or other upper<br>respiratory allergies <b>u</b> temporarily relieves<br>these symptoms due to hay fever (allergic<br>rhinitis): • sneezing • itching of the nose or<br>throat • runny nose • itchy, watery eyes<br><b>u</b> temporarily restores freer breathing     | BROMPHENIRAMINE<br>MALEATE<br>Antihistamine<br>DEXTROMETHORPHAN HBr                       | Age     Dose       adults & children 12 years & 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 10 |
| through the nose<br>Warnings<br>Do not use ■ to sedate a child or to make<br>a child sleepy ■ if you are now taking a<br>prescription monoamine oxidase inhibitor  | Cough suppressant<br>PHENYLEPHRINE HCI<br>Nasal decongestant<br>DM Liquid<br>Alcohol free | mg ■ store at 20-25°C (68-77°F) ■ measuring cup provided<br>Keep carton for complete information.<br>Distributed by:<br>CVS Pharmacy, Inc.<br>One CVS Drive  |
| (MAOI) (certain drugs for depression,<br>psychiatric, or emotional conditions, or<br>Parkinson's • Drug Facts continued on other panel   | 6+ Years Grape  |  |

| CHILDRENS COLD AN<br>brompheniramine maleate, de   |                                   | nylephrine ho | :l liquid                        |               |                   |  |
|--|-----------------------------------|---------------|----------------------------------|---------------|-------------------|--|
|  |                                   |               |                                  |               |                   |  |
| Product Information  |                                   |               |                                  |               |                   |  |
| Product Type   | HUMAN OTC DRUG Item Code (Source) |               |                                  | NDC:51316-578 |                   |  |
| Route of Administration  | ORAL                              |               |                                  |               |                   |  |
|  |                                   |               |                                  |               |                   |  |
|  | N                                 |               |                                  |               |                   |  |
| Active Ingredient/Active   | -                                 |               |                                  |               |                   |  |
| Ingred   | lient Name                        |               | Basis of Str                     | ength         | Strength          |  |
| <b>BROMPHENIRAMINE MALEATE</b> (UNII: IXA7C9ZN03) (BROMPHENIRAMINE - UNII: H57G17P2FN)           |                                   |               | BROMPHENIRAMINE<br>MALEATE       |               | 2 mg<br>in 10 mL  |  |
|  |                                   |               | DEXTROMETHORPHAN<br>HYDROBROMIDE |               | 10 mg<br>in 10 mL |  |
| PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS 297W6MV) PHENYLEPHRINE |                                   |               |                                  |               | 5 mg<br>in 10 mL  |  |
|  |                                   |               |                                  |               |                   |  |
| Inactive Ingredients   |                                   |               |                                  |               |                   |  |
| Ingredient Name  |                                   |               |                                  |               | Strength          |  |
| ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)   |                                   |               |                                  |               | _                 |  |
| FD&C BLUE NO. 1 (UNII: H3R47K3   | TBD)                              |               |                                  |               |                   |  |
| FD&C RED NO. 40 (UNII: WZ B9127  | 7XOA)                             |               |                                  |               |                   |  |
| GLYCERIN (UNII: PDC6A3C0OX)  |                                   |               |                                  |               |                   |  |

| PR                                 | <b>OPYLENE GLYC</b>                           | <b>OL</b> (UNII: 6DC9                      | Q167V3)                 |           |                         |                       |
|------------------------------------|---|--|-------------------------|-----------|-------------------------|-----------------------|
| WATER (UNII: 059QF0K00R)           |   |  |                         |           |                         |                       |
| SODIUM BENZOATE (UNII: OJ245FE5EU) |   |  |                         |           |                         |                       |
| SORBITOL (UNII: 506T60A25R)        |   |  |                         |           |                         |                       |
| SUCRALOSE (UNII: 96K6UQ3ZD4)       |   |  |                         |           |                         |                       |
| PROPYL GALLATE (UNII: 8D4SNN7V92)  |   |  |                         |           |                         |                       |
| sc                                 | DIUM CITRATE                                  | (UNII: 1Q73Q2JI                            | ULR)                    |           |                         |                       |
|                                    |   |  |                         |           |                         |                       |
| Pı                                 | oduct Chara                                   | acteristics                                |                         |           |                         |                       |
| Сс                                 | lor   |  | PURPLE                  | Score     |                         |                       |
| Sł                                 | ape   |  |                         | Size      |                         |                       |
|                                    | avor  |  | GRAPE                   | Imprint 0 | Code                    |                       |
| Contains                           |   |  |                         |           |                         |                       |
| Co                                 | ntains  |  |                         |           |                         |                       |
| Co                                 | ntains  |  |                         |           |                         |                       |
| Co                                 | ntains  |  |                         |           |                         |                       |
|                                    | ntains<br>ackaging                            |  |                         |           |                         |                       |
| Pa                                 |   | Pa   | ckage Description       |           | Marketing Start<br>Date | Marketing End<br>Date |
| Pa<br>#                            | ackaging                                      |  |                         |           |                         | -                     |
| Pa<br>#                            | ackaging<br>Item Code<br>NDC:51316-578-       | 1 in 1 CARTON                              |                         |           | Date                    | -                     |
| <b>P</b> a<br>#                    | ackaging<br>Item Code<br>NDC:51316-578-       | 1 in 1 CARTON<br>118 mL in 1 B0            |                         |           | Date                    | -                     |
| <b>P</b> a<br>#                    | ackaging<br>Item Code<br>NDC:51316-578-       | 1 in 1 CARTON<br>118 mL in 1 B0            |                         |           | Date                    | -                     |
| Pa<br>#<br>1                       | ackaging<br>Item Code<br>NDC:51316-578-       | 1 in 1 CARTON<br>118 mL in 1 BO<br>Product | DTTLE; Type 0: Not a Co |           | Date                    | -                     |
| Pa<br>#<br>1                       | ackaging<br>Item Code<br>NDC:51316-578-<br>03 | 1 in 1 CARTON<br>118 mL in 1 BC<br>Product | DTTLE; Type 0: Not a Co | mbination | Date                    | -                     |

# Labeler - CVS (062312574)

| Establishment         |         |           |                            |  |  |  |
|-----------------------|---------|-----------|----------------------------|--|--|--|
| Name                  | Address | ID/FEI    | <b>Business Operations</b> |  |  |  |
| Guardian Drug Company |         | 119210276 | MANUFACTURE(51316-578)     |  |  |  |

Revised: 1/2025