# CONGESTION AND COUGH CHILDRENS- dextromethorphan hbr, guaifenesin, phenylephrine hcl solution CVS PHARMACY

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CVS 44-056

#### Active ingredients (in each 5 mL)

Dextromethorphan HBr 5 mg Guaifenesin 100 mg Phenylephrine HCl 2.5 mg

#### **Purpose**

Cough suppressant Expectorant Nasal decongestant

#### Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
- temporarily relieves:
  - cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants
  - stuffy nose
  - nasal congestion due to a cold
  - the intensity of coughing
  - the impulse to cough to help the child get to sleep

# Warnings

#### Do not use

in a child who is 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 child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.

#### Ask a doctor before use if the child has

- diabetes
- heart disease
- thyroid disease
- high blood pressure
- persistent or chronic cough such as occurs with asthma
- cough that occurs with too much phlegm (mucus)

#### When using this product

do not exceed recommended dosage.

#### Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- symptoms do not get better within 7 days or occur with fever
- cough persists more than 7 days, tends to recur, or is accompanied by a fever, rash, or persistent headache. These could be signs of a serious condition.

#### 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 directed
- do not take more than 6 doses in any 24-hour period
- mL = milliliter
- only use the dose cup provided
- dose as follows or as directed by a doctor

| Age                          | Dose                |
|------------------------------|---------------------|
| children 6 to under 12 years | 10 mL every 4 hours |
| children 4 to under 6 years  | 5 mL every 4 hours  |
| children under 4 years       | do not use          |

#### Other information

- each 5 mL contains: sodium 3 mg
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

# Inactive ingredients

anhydrous citric acid, FD&C red #40, flavors, glycerin, propylene glycol, purified water, sodium benzoate, sodium citrate dihydrate, sorbitol, sucralose, xanthan gum

#### Questions or comments?

1-800-426-9391

### Principal display panel

#### **VCVS**

Health<sub>®</sub>

#### Children's Cough &

#### Congestion

#### **DEXTROMETHORPHAN HBr**

Cough suppressant

#### **GUAIFENESIN**

Expectorant

#### PHENYLEPHRINE HCI

Nasal decongestant

#### **Oral Solution**

#### Relieves:

- Chest congestion
- Stuffy nose
- Cough

Breaks up mucus

No added alcohol Free of high fructose corn syrup, sugar, aspirin & ibuprofen

# For Ages 4 to 11 Years

Berry Flavor Dosage cup included Actual Bottle Size on Side Panel

#### 6.8 FL OZ (201 mL)

# TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

#### **PARENTS:**

Learn about teen medicine abuse www.StopMedicineAbuse.org

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### **CONGESTION AND COUGH CHILDRENS**

dextromethorphan hbr, quaifenesin, phenylephrine hcl solution

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:69842-756

| Active Ingredient/Active Moiety  |                                  |                   |  |
|--|----------------------------------|-------------------|--|
| Ingredient Name  | Basis of Strength                | Strength          |  |
| <b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN<br>HYDROBROMIDE | 5 mg<br>in 5 mL   |  |
| GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)                               | GUAIFENESIN                      | 100 mg<br>in 5 mL |  |
| PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)            | PHENYLEPHRINE<br>HYDROCHLORIDE   | 2.5 mg<br>in 5 mL |  |

| Inactive Ingredients                           |          |  |
|--|----------|--|
| Ingredient Name                                | Strength |  |
| ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)       |          |  |
| 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)                   |          |  |
| XANTHAN GUM (UNII: TTV12P4NEE)                 |          |  |

| Product Characteristics |       |              |  |
|-------------------------|-------|--------------|--|
| Color                   | red   | Score        |  |
| Shape                   |       | Size         |  |
| Flavor                  | BERRY | Imprint Code |  |
| Contains                |       |              |  |

| Packaging            |  |                         |                       |  |
|----------------------|--|-------------------------|-----------------------|--|
| # Item Code          | Package Description  | Marketing Start<br>Date | Marketing End<br>Date |  |
| NDC:69842-<br>756-88 | 1 in 1 CARTON  | 07/01/2018              |                       |  |
| 1                    | 201 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product |                         |                       |  |

| Marketing Information |   |                         |                       |  |
|-----------------------|---|-------------------------|-----------------------|--|
| Marketing<br>Category | Application Number or Monograph<br>Citation | Marketing Start<br>Date | Marketing End<br>Date |  |
| OTC Monograph Drug    | M012  | 07/01/2018              |                       |  |
|                       |   |                         |                       |  |

# Labeler - CVS PHARMACY (062312574)

| Establishment           |         |           |  |
|-------------------------|---------|-----------|--|
| Name                    | Address | ID/FEI    | Business Operations                      |
| LNK International, Inc. |         | 967626305 | manufacture(69842-756) , pack(69842-756) |

Revised: 5/2023 CVS PHARMACY