COLD CHILDRENS, MULTI SYMPTOM- dextromethorphan hbr, guaifenesin, phenylephrine hcl solution CVS PHARMACY

CVS 44-057

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 | 10 mL every 4 |
| years | hours |
| children 4 to under 6 | 5 mL every 4 |
| years | 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

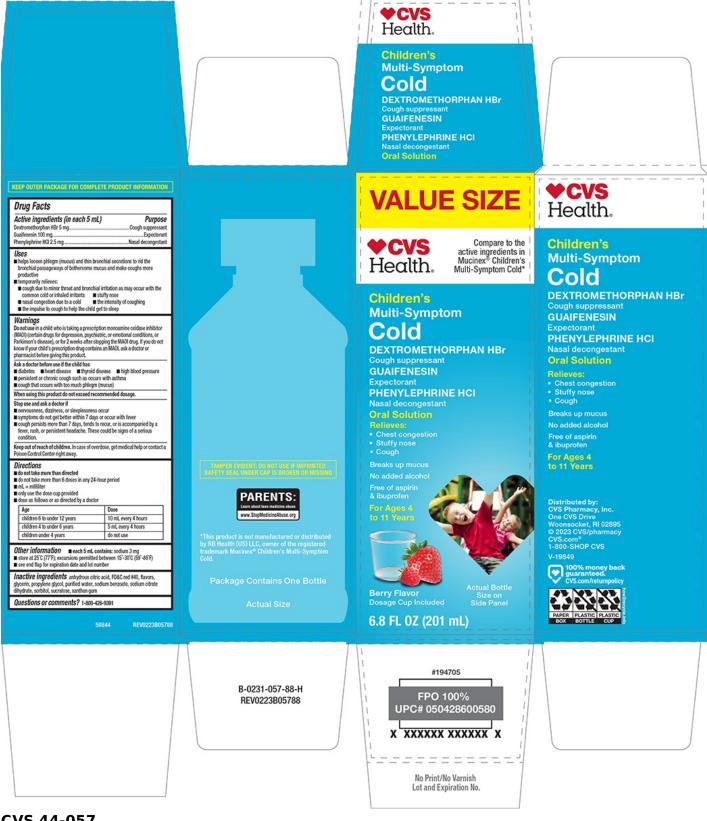
Inactive ingredients

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



CVS 44-057 VALUE SIZE

VCVS

Health_®

Compare to the active ingredients in Mucinex® Children's

Multi-Symptom Cold*

Children's Multi-Symptom Cold

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 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

*This product is not manufactured or distributed by RB Health (US) LLC, owner of the registered trademark Mucinex® Children's Multi-Symptom Cold.

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COLD CHILDRENS, MULTI SYMPTOM

dextromethorphan hbr, guaifenesin, phenylephrine hcl solution

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:69842-570

Route of Administration ORAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength Strength **DEXTROMETHORPHAN HYDROBROMIDE** (UNII: 9D2RTI9KYH) **DEXTROMETHORPHAN** 5 mg (DEXTROMETHORPHAN - UNII:7355X3ROTS) HYDROBROMIDE in 5 mL 100 mg GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ) **GUAIFENES IN** in 5 mL PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE -**PHENYLEPHRINE** 2.5 mg UNII:1WS297W6MV) **HYDROCHLORIDE** 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 Date | Marketing End Date |
| | 1 NDC:69842-570-88 | 1 in 1 CARTON | 07/31/2018 | |
| | 1 | 201 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | | |
| Н | | Combination Froduct | | |

| Marketing Information | | | |
|-----------------------|---|-------------------------|-----------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC Monograph Drug | M012 | 07/31/2018 | |
| | | | |

Labeler - CVS PHARMACY (062312574)

| Establishment | | | |
|-------------------------|---------|-----------|--|
| Name | Address | ID/FEI | Business Operations |
| LNK International, Inc. | | 967626305 | manufacture(69842-570) , pack(69842-570) |

Revised: 5/2023 CVS PHARMACY