CHEST CONGESTION CHILDRENS PLUS COUGH- dextromethorphan hydrobromide, guaifenes in solution CVS Pharmacy

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.

CVS Pharmacy, Inc. Children's Chest Congestion Plus Cough Drug Facts

Active ingredients (in each 5 mL)

Dextromethorphan HBr 5 mg Guaifenesin 100 mg

Purpose

Cough suppressant

Expectorant

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
- the intensity of coughing
- the impulse to cough to help your 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

- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such as occurs with asthma

Stop use and ask a doctor if

cough lasts more than 7 days, comes back, or occurs with 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 (1-800-222-1222).

Directions

- do not take more than 6 doses in any 24-hour period
- measure only with dosing cup provided
- do not use dosing cup with other products
- mL = milliliter

| Age | Dose |
|------------------------------------|-----------------------------|
| children 6 years to under 12 years | 5 mL - 10 mL every 4 hours |
| children 4 years to under 6 years | 2.5 mL – 5 mL every 4 hours |
| children under 4 years | do not use |

Other information

- do not use if printed neckband is broken or missing
- store at 20-25°C (68-77°F)
- do not refrigerate
- dosing cup provided

Inactive ingredients

acesulfame potassium, anhydrous citric acid, D&C red #33, FD&C red #40, flavor, glycerin, maltitol solution, propylene glycol, purified water, saccharin sodium, sodium benzoate, sorbitol solution, xanthan gum

Questions or comments?

1-800-719-9260

Principal Display Panel

Compare to the active ingredients in Children's Mucinex® Cough

Children's

Mucus Relief

Chest Congestion Plus Cough

DEXTROMETHORPHAN HBr

Cough suppressant

GUAIFENESIN

Expectorant

Relieves: Chest congestion & cough

Thins & loosens mucus

Alcohol free

For Ages 4 to 12 Years

Cherry Flavor Liquid



♥CVS

Compare to the active ingredients in Children's Mucinex® Cough* NDC 59779-419-26

Plus Cough Congestion Chest Mucus Relief

Children's

◆C\2Health.

♥CVS Health.

Children's

Chest

GUAIFENESIN

Expectorant

Alcohol free

Mucus Relief

Congestion

Plus Cough

DEXTROMETHORPHAN HBr

Chest congestion & cough

Thins & loosens mucus

Cherry Flavor Liquid

4 FL OZ (118 mL)

Dosage cup included



Health. Children's

Chest

Cough suppressa GUAIFENESIN

Expectorant

Alcohol free

Mucus Relief

Congestion

Plus Cough

DEXTROMETHORPHAN HBr

Chest congestion & cough

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Drug Facts (continued)

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'This product is not manufactured or distributed by Reckitt Benckiser, distributor of Children's Mucinex® Cough.

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LOT NO.

EXP.

: 41926 17 C5

CHEST CONGESTION CHILDRENS PLUS COUGH

dextromethorphan hydrobromide, guaifenesin solution

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:59779-419

| Active Ingredient/Active Moiety | | | |
|--|----------------------------------|-------------------|--|
| Ingredient Name | Basis of Strength | Strength | |
| DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9 D2RTI9 KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 5 mg in 5 mL | |
| GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ) | GUAIFENESIN | 100 mg in 5 mL | |

| Inactive Ingredients | | |
|---|----------|--|
| Ingredient Name | Strength | |
| ACESULFAME POTASSIUM (UNII: 23OV73Q5G9) | | |
| ANHYDRO US CITRIC ACID (UNII: XF417D3PSL) | | |
| D&C RED NO. 33 (UNII: 9DBA0SBB0L) | | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | |
| MALTITOL (UNII: D65DG142WK) | | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | | |
| WATER (UNII: 059QF0KO0R) | | |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY) | | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | | |
| SORBITOL (UNII: 506T60A25R) | | |
| XANTHAN GUM (UNII: TTV12P4NEE) | | |

| Product Characteristics | | | |
|-------------------------|----------------|--------------|--|
| Color | RED (Dark Red) | Score | |
| Shape | | Size | |
| Flavor | CHERRY | Imprint Code | |
| Contains | | | |

| Packaging | | | |
|--------------------|---|-----------------------------|--------------------|
| # Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 NDC:59779-419-26 | 1 in 1 CARTON | 03/11/2009 | |
| 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 | 03/11/2009 | |
| | | | |

Labeler - CVS Pharmacy (062312574)

Revised: 11/2016 CVS Pharmacy