

# **CHILDRENS MUCUS AND COUGH RELIEF- guaifenesin and dextromethorphan hydrobromide liquid**

**Chain Drug Manufacturing Assn**

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**Quality Choice Children's Mucus &**

**Cough Relief Cherry Flavor 4 FL OZ  
(118 mL)**

## ***Drug Facts***

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| <b><i>Active ingredients (in each 5 mL)</i></b> | <b><i>Purposes</i></b> |
|---|------------------------|
| Dextromethorphan HBr 5 mg                       | Cough suppressant      |
| Guaifenesin 100 mg                              | Expectorant            |

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## **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 illness.

**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 dosing cup provided
- do not use dosing cup with other products

- mL = milliliter

| <b>Age</b>                         | <b>Dose</b>                 |
|------------------------------------|-----------------------------|
| 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**

- each 5 mL contains: **sodium 3 mg**
- Tamper -evident: do not use if printed inner seal under cap is torn or missing
- store at room temperature
- do not refrigerate
- dosing cup provided

### **Inactive ingredients**

Anhydrous citric acid, edetate disodium, FD&C Red#40, flavors, potassium citrate, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, xanthan gum

### **PRINCIPAL DISPLAY PANEL - 118 mL Bottle Carton**

NDC 63868-771-04

Compare to the Active ingredient in Children's Mucinex Cough\*

### **Children's**

### **Mucus & Cough Relief**

### **Cough Suppressant**

### **Expectorant**

Dextromethorphan HBr

Guaifenesin

Each Dose of Cherry Flavored

Children's

Mucus & Cough Relief:

Controls Cough

Relieves Chest Congestion

Breaks up Mucus

Alcohol-free

See New Dosing information

**Cherry  
Flavor**

**4 FL OZ  
(118 mL)**

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

DOSAGE CUP INCLUDED

Distributed by C.D.M.A., Inc©

43157 W. Nine Mile

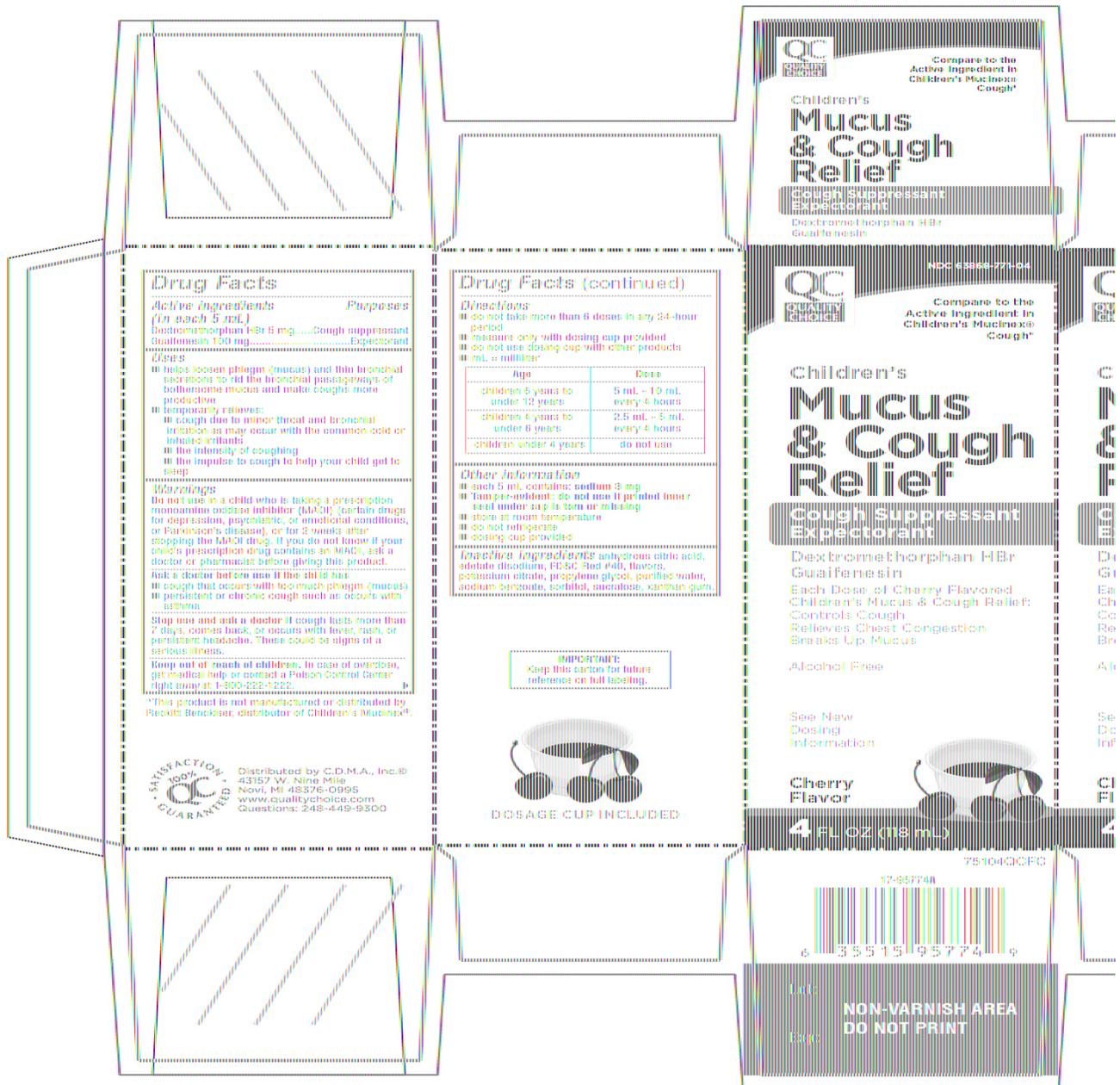
Novi, MI 48376-0995

[www.qualitychoice.com](http://www.qualitychoice.com)

Questions: 248-449-9300

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

QC 100% Satisfaction Guaranteed.



## CHILDRENS MUCUS AND COUGH RELIEF

guaifenesin and dextromethorphan hydrobromide liquid

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:63868-771 |
| <b>Route of Administration</b> | ORAL           |                           |               |

### Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength                | Strength          |
|---|----------------------------------|-------------------|
| <b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RT19KYH)<br>(DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN<br>HYDROBROMIDE | 5 mg<br>in 5 mL   |
| <b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)                           | GUAIFENESIN                      | 100 mg<br>in 5 mL |

## Inactive Ingredients

| Ingredient Name                                 | Strength |
|---|----------|
| <b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL) |          |
| <b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)      |          |
| <b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)   |          |
| <b>POTASSIUM CITRATE</b> (UNII: EE90ONI6FF)     |          |
| <b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)      |          |
| <b>WATER</b> (UNII: 059QF0KO0R)                 |          |
| <b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)       |          |
| <b>SORBITOL</b> (UNII: 506T60A25R)              |          |
| <b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)             |          |
| <b>XANTHAN GUM</b> (UNII: TTV12P4NEE)           |          |

## Product Characteristics

|                 |        |                     |  |
|-----------------|--------|---------------------|--|
| <b>Color</b>    | red    | <b>Score</b>        |  |
| <b>Shape</b>    |        | <b>Size</b>         |  |
| <b>Flavor</b>   | CHERRY | <b>Imprint Code</b> |  |
| <b>Contains</b> |        |                     |  |

## Packaging

| # | Item Code        | Package Description                                   | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:63868-771-04 | 1 in 1 CARTON   | 10/19/2015           |                    |
| 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 Drug | M012                                     | 10/19/2015           |                    |

**Labeler** - Chain Drug Manufacturing Assn (011920774)