

CHILDRENS MUCINEX COUGH- guaifenesin and dextromethorphan hydrobromide liquid
Reckitt Benckiser LLC

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.

**Children's
Mucinex®
Cough**

Drug Facts

| <i>Active ingredients (in each 5 mL)</i> | <i>Purpose</i> |
|---|-----------------------|
| Dextromethorphan HBr 5 mg | Cough suppressant |
| Guaifenesin 100 mg | 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 illness.

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 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

- tamper evident: do not use if printed neckband on bottle cap is broken or missing
- store between 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, propylene glycol, purified water, saccharin sodium, sodium benzoate, sorbitol, xanthan gum

Questions?

1-866-MUCINEX (1-866-682-4639)

You may also report side effects to this phone number.

Dist. by: Reckitt Benckiser, Parsippany, NJ 07054-0224

PRINCIPAL DISPLAY PANEL - 118 mL Bottle Carton

NDC 63824-281-64

**Children's
Mucinex®**

Cough

Guaifenesin 100 mg

Dextromethorphan HBr 5 mg

Expectorant

Cough Suppressant

☐ **Cough**

☐ **Chest Congestion**

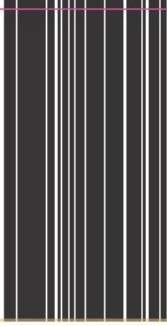
☐ **Breaks up Mucus**

☐ **Alcohol-free**

**Cherry
Flavor Liquid**

**4 FL OZ
(118 mL)**

232M926L9



Tamper evident: do not use if printed neckband on bottle cap is broken or missing.

Children's MucinEX[®]

Cough

Guaifenesin 100 mg
Dextromethorphan HBr 5 mg
Expectorant
Cough Suppressant

NDC 63824-281-64

Children's MucinEX[®]

Children's MucinEX[®]

Cough

Guaifenesin 100 mg
Dextromethorphan HBr 5 mg
Expectorant
Cough Suppressant

- ✓ Cough
- ✓ Chest Congestion
- ✓ Breaks up Mucus
- ✓ Alcohol-free

Cough



DOSING CUP INCLUDED

Each dose of Children's MucinEX[®] Cough Liquid:

- ✓ Controls Cough
- ✓ Relieves Chest Congestion
- ✓ Breaks up Mucus
- ✓ Alcohol-free

Questions or comments?
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or www.mucinex.com

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Drug Facts (continued)

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PARENTS:
Learn about teen medicine abuse

www.StopMedicineAbuse.org

Also look for
Children's MucinEX[®]

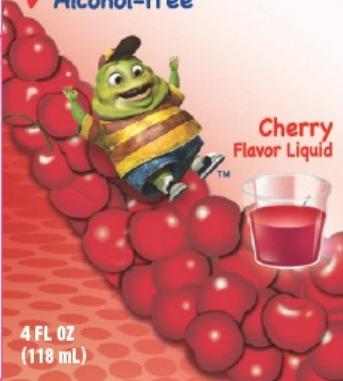
mini-melts

Great-tasting chest-congestion relief in fun-to-take, convenient granule packets!

Reckitt Benckiser

100312
8058245

Dist. by: Reckitt Benckiser, Parsippany, NJ 07054-0224 ©RFB 2012



Cherry Flavor Liquid

4 FL OZ
(118 mL)

41926W2C2



LOT NO.

EXP.

: 41926 W2 C2



CHILDRENS MUCINEX COUGH

guaifenesin and dextromethorphan hydrobromide liquid

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:63824-281

Route of Administration

ORAL

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|----------------------------------|-------------------|
| GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ) | GUAIFENESIN | 100 mg in 5 mL |
| DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 5 mg in 5 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| ACESULFAME POTASSIUM (UNII: 23OV73Q5G9) | |
| ANHYDROUS 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: 059QF0K00R) | |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY) | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | |
| SORBITOL (UNII: 506T60A25R) | |
| XANTHAN GUM (UNII: TTV12P4NEE) | |

Product Characteristics

| | | | |
|----------|--------|--------------|--|
| Color | RED | Score | |
| Shape | | Size | |
| Flavor | CHERRY | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:63824-281-64 | 1 in 1 CARTON | | |
| 1 | | 118 mL in 1 BOTTLE | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC MONOGRAPH FINAL | part341 | 07/01/2011 | |

Labeler - Reckitt Benckiser LLC (094405024)