LEADER CHILDRENS MUCUS RELIEF- dextromethorphan hbr, guaifenesin, phenylephrine hcl solution Cardinal Health 110, LLC. dba Leader

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.

Cardinal Health Children's Mucus Relief Drug Facts

Active ingredients (in each 5 mL)

Dextromethorphan HBr 5 mg

Guaifenesin 100 mg

Phenylephrine HCl 2.5 mg

Purposes

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
- the intensity of coughing
- the impulse to cough to help your child get to sleep
- nasal congestion due to a cold
- stuffy nose

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

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

When using this product

do not use more than directed

Stop use and ask a doctor if

- your child gets nervous, dizzy or sleepless
- symptoms do not get better within 7 days or occur with fever
- 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
- dose as follows or as directed by a doctor
- mL = milliliter

| Age | Dose |
|------------------------------------|---------------------|
| children 6 years to under 12 years | 10 mL every 4 hours |
| children 4 years 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
- 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

anhydrous citric acid, edetate disodium, FD&C red #40, flavor, glycerin, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol solution, sucralose, xanthan gum

Questions or comments?

1-800-719-9260

Package/Label Principal Display Panel

Children's Mucus Relief Multi-Symptom Cold Dextromethorphan HBr Cough Suppressant Guaifenesin Expectorant Phenylephrine HCl Nasal Decongestant Berry Flavor Ages 4-12 Years COMPARE TO CHILDREN'S MUCINEX® MULTI-SYMPTOM COLD active ingredients Relief of: Stuffy Nose Cough Chest Congestion Breaks Up Mucus 4 FL OZ (118 mL)

LEADER? LEADER?

Children's Mucus Relief Multi-Symptom Cold

Dextromethorphan HBr Cough Suppressant Guaifenesin Expectorant Phenylephrine HCI

Nasal Decongestant

Berry

Ages 4-12 Years

Relief Of: Stuffy Nose Cough Chest Congestion Breaks Up Mucus COMPARE TO CHILDREN'S MUCINEX® MULTI-SYMPTOM COLD active ingredients*

100% Money Back Guarantee

4 FL OZ (118 mL)

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Children's

Mucus

Relief

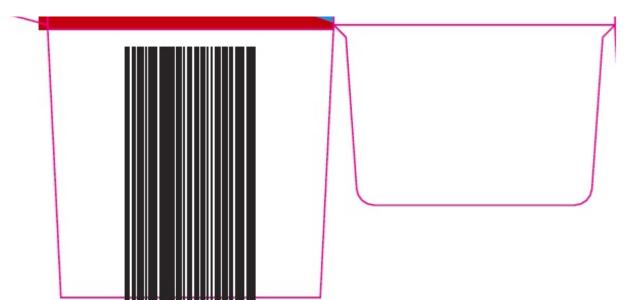
Cold

Multi-Symptom

DISTRIBUTED BY CARDINAL HEALTH DUBLIN, OHIO 43017 www.myleader.com 1-800-200-6313 Essential to Care™ since 1979

> All LEADER™ Brand Products Have A 100% Money Back Guarantee

Return to place of purchase if not satisfied.





children's

серрек

Drug Facts

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|---|----------|
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Questions or comments? 1-800-719-9260

Gluten Free

*This product is not manufactured or distributed by Reckitt Benckiser LLC, owner of the registered trademark Mucinex®.



www.StopMedicineAbuse.org

| CIN 5320809 REV. 3/17 | |
|-----------------------|--|
| LOT NO. | |
| EXP. | |
| : 63926 E9 C3 | |

| dextromethorphan hbr, guaife | enesin, phenylephrine | hcl solution | | | | |
|--|---|------------------------|--|----------|-------------------|--|
| Droduct Information | | | | | | |
| | oduct Information | | | | | |
| Product Type | HUMAN OTC DRUG | Item Code (Source) NDC | | NDC:7000 | 2:70000-0261 | |
| Route of Administration | ORAL | | | | | |
| | | | | | | |
| Active Ingredient/Active | Moiety | | | | | |
| Ingre | dient Name | | Basis of St | rength | Strength | |
| DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | | | DEXTROMETHORPHAN HYDROBROMIDE | | 5 mg in 5 mL | |
| GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ) | | | GUAIFENESIN | | 100 mg in 5 mL | |
| PHENYLEPHRINE HYDROCHLOR UNII:1WS297W6MV) | DE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - | | PHENYLEPHRINE HYDROCHLORIDE | | 2.5 mg in 5 mL | |
| | | | | | | |
| Inactive Ingredients | | | | | | |
| Ingredient Name | | | | | Strength | |
| | | | ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) | | | |
| ANHYDROUS CITRIC ACID (UNII: | XF417D3PSL) | | | | | |
| ANHYDROUS CITRIC ACID (UNII: EDETATE DISODIUM (UNII: 7FLD9 | | | | | | |
| • | 1C86K) | | | | | |
| EDETATE DISODIUM (UNII: 7FLD9 | 1C86K) | | | | | |
| EDETATE DISODIUM (UNII: 7FLD9 FD&C RED NO. 40 (UNII: WZ B912 GLYCERIN (UNII: PDC6A3C0OX) PROPYLENE GLYCOL (UNII: 6DC9 | 1C86K) 7XOA) | | | | | |
| EDETATE DISODIUM (UNII: 7FLD9 FD&C RED NO. 40 (UNII: WZ B912 GLYCERIN (UNII: PDC6A3C0OX) PROPYLENE GLYCOL (UNII: 6DC9 WATER (UNII: 059QF0KO0R) | 1C86K) 7XOA) Q167V3) | | | | | |
| EDETATE DISODIUM (UNII: 7FLD9 FD&C RED NO. 40 (UNII: WZ B912 GLYCERIN (UNII: PDC6A3C0OX) PROPYLENE GLYCOL (UNII: 6DC9 WATER (UNII: 059QF0K00R) SODIUM BENZOATE (UNII: 0J2451 | 1C86K) 7XOA) Q167V3) =E5EU) | | | | | |
| EDETATE DISODIUM (UNII: 7FLD9 FD&C RED NO. 40 (UNII: WZ B912 GLYCERIN (UNII: PDC6A3C0OX) PROPYLENE GLYCOL (UNII: 6DC9 WATER (UNII: 059QF0KO0R) SODIUM BENZOATE (UNII: 0J2451 SODIUM CITRATE, UNSPECIFIED | 1C86K) 7XOA) Q167V3) =E5EU) |) | | | | |
| EDETATE DISODIUM (UNII: 7FLD9 FD&C RED NO. 40 (UNII: WZ B912 GLYCERIN (UNII: PDC6A3C0OX) PROPYLENE GLYCOL (UNII: 6DC9 WATER (UNII: 059QF0K00R) SODIUM BENZOATE (UNII: 0J2451 | 1C86K) 7XOA) Q167V3) =E5EU) |) | | | | |

| Product Char | acteristic | S | | | | |
|-------------------------------|------------------------|------------------------------------|--------------|-------------------------|-------------------|---|
| Color | | RED (clear) | Score | | | |
| Shape | | | Size | | | |
| Flavor | | BERRY | Imprint Code | | | |
| Contains | | | | | | |
| | | | | | | |
| Packaging | | | | | | |
| # Item Code | | Package Description | | Marketing Start Date | Marketing Date | - |
| 1 NDC:70000- 0261-1 | 1 in 1 CART | RTON | | 03/22/2017 | | |
| 1 | 118 mL in 1 Product | BOTTLE; Type 0: Not a Combi | nation | | | |
| | | | | | | |
| Marketing | Informa | ation | | | | |
| Marketing | Appli | cation Number or Monog Citation | raph | Marketing Start Date | Marketin Date | |
| Category | | Citation | | | | - |

Labeler - Cardinal Health 110, LLC. dba Leader (063997360)

Revised: 6/2021

Cardinal Health 110, LLC. dba Leader