

**CHILDRENS MUCUS AND COUGH RELIEF - dextromethorphan hbr,
guaifenesin liquid
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.

Leader Childrens Mucus and Cough

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 drain bronchial tubes and make coughs more productive
- temporarily relieves:
 - cough due to minor throat and bronchial irritation as may occur with a cold or inhaled irritants
 - the impulse to cough to help your child get to sleep
 - the intensity of coughing

WARNING

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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

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

STOP USE AND ASK A DOCTOR IF

- cough lasts more than 7 days, comes back, or is accompanied by 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 (1-800-222-1222) 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

- **each 5 mL contains:** potassium 5 mg, sodium 5 mg
- store between 20 to 25°C (68 to 77°F)
- do not refrigerate
- dosing cup provided

INACTIVE INGREDIENTS

citric acid anhydrous, dextrose, D&C red#33, FD&C red#40, flavor, glycerin, methylparaben, potassium sorbate, propylene glycol, propyl paraben, purified water, saccharin sodium, sodium hydroxide, sorbitol, sucralose, xanthan gum

QUESTIONS COMMENTS?

call (609) 860-2600 Mon - Fri 8:00 am to 4:30 pm est

PRINCIPAL DISPLAY PANEL

LEADER

NDC 70000-0630-1

Children's Mucus & Cough Relief

Dextromethorphan HBr, 5mg

Guaifenesin 100 mg

cough Suppressant

Expectorant

Cherry Flavor

Ages 4+ Years

Controls Cough

Relieves Chest Congestion

Thins and Loosen Mucus

COMPARE TO CHILDREN'S MUCINEX[®] COUGH

active ingredients*

4 FL OZ (118mL)

No Coating Area

COATING FREE AREA

Glue

Drug Facts

Active ingredients (in each 5 mL): Purpose
Dextromethorphan HBr, 5 mg
Guaifenesin, 100 mg
Expectorant

Uses

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- temporarily relieves
 - cough due to minor throat and bronchial irritation as may occur with a cold or influenza
 - the impulse to cough to help your child get to sleep
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Ask a doctor before use if the child has

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- cough that occurs with too much phlegm (mucus)

Stop use and ask a doctor if

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- do not use dosing cup with other products
- mL - milliliter

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Dextromethorphan HBr, 5 mg
Guaifenesin, 100 mg
Cough Suppressant | Expectorant

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DC 7209-3630-1

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Guaifenesin, 100 mg
Cough Suppressant
Expectorant

Cherry Flavor

Ages 4+ Years

Controls Cough

Relieves Chest Congestion

Thins and Loosens Mucus



COMPARE TO CHILDREN'S MUCINEX[®] COUGH active ingredients*

100% Money Back Guarantee

4 FL OZ (118 mL)

Children's Mucus & Cough Relief

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CARDINAL HEALTH
DUBLIN, OHIO 43077
www.mucinex.com
1-800-204-0815
Essential to Care[®] since 1975

Cardinal health™

All LEADER[™] Brand Products Have A 100% Money Back Guarantee. Return to place of purchase if not satisfied.



LOT:

UNFINISHED AREA TO BE LEFT BLANK FOR LOT & EXP. INFORMATION

EXP:

DO NOT USE IF SEAL UNDER CAP IMPRINTED WITH "SEALED FOR YOUR PROTECTION" IS BROKEN OR MISSING.

Drug Facts

Active ingredients (in each 5 mL) Purpose
 Dextromethorphan HBr 5 mg.....Cough suppressant
 Guaifenesin 100 mg.....Expectorant

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NDC 70000-0630-1

Children's Mucus & Cough Relief

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 Cough Suppressant | Expectorant

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 Thins and Loosens Mucus

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Drug Facts (continued)

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

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Other information ■ each 5 mL contains: potassium 5 mg, sodium 5 mg ■ store between 20-25°C (68-77°F) ■ do not refrigerate ■ dosing cup provided

Refer to carton for full labeling information

MFR# 53041

DIST BY CAH DUBLIN, OH 43007
 www.myleader.com 1-800-200-5313

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CIN 5620014 REV. 1/23

LOT:

EXP:

CHILDRENS MUCUS AND COUGH RELIEF

dextromethorphan hbr, guaifenesin liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0630
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	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

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	

FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
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:70000-0630-1	1 in 1 CARTON	03/22/2023	
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	03/22/2023	

Labeler - CARDINAL HEALTH 110, LLC. DBA LEADER (063997360)

Establishment

Name	Address	ID/FEI	Business Operations
Guardian Drug Company		119210276	MANUFACTURE(70000-0630)