

**LEADER CHILDRENS MUCUS AND COUGH RELIEF- dextromethorphan hbr,
guaifenesin 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 & Cough Relief 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

Children's Mucus & Cough Relief

Guaifenesin, 100 mg

Dextromethorphan HBr, 5 mg

Expectorant | Cough Suppressant

Cherry Flavor Liquid

Age 4+

Cough

Chest Congestion

Loosens Mucus

Alcohol-Free

COMPARE TO CHILDREN'S MUCINEX® COUGH active ingredients

100% Money Back Guarantee

4 FL OZ (118 mL)



LEADER CHILDRENS MUCUS AND COUGH RELIEF

dextromethorphan hbr, guaifenesin solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0008
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
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
XANTHAN GUM (UNII: TTV12P4NEE)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	

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:70000-0008-1	1 in 1 CARTON	01/28/2020	
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	01/28/2020	

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

Revised: 6/2021

Cardinal Health 110, LLC. dba Leader