

**LEADER CHILDRENS MULTI SYMPTOM COLD - dextromethorphan hbr,
guaifenesin, phenylephrine hcl 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 Multi Symptoms Cold 615

ACTIVE INGREDIENTS (in each 5 mL)

Dextromethorphan HBr 5 mg

Guaifenesin 100 mg

Phenylephrine HCl 2.5 mg

PURPOSE

Cough suppressant

Expectorant

Nasal decongestant

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

WHEN USING THIS PRODUCT

- **do not use more than directed**

STOP USE AND ASK 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 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
- dose as follows or as directed by a doctor

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

- mL=milliliter

OTHER INFORMATION

- **each 5 mL contains:** potassium 5 mg, sodium 5 mg
- store between 15-30 °C (59-86 °F)
- do not refrigerate
- dosing cup provided

INACTIVE INGREDIENTS

citric acid anhydrous, D&C red #33, dextrose, edetate disodium, FD&C blue #1, FD&C red #40, flavor, glycerin, methylparaben, potassium sorbate, propyl gallate, propylene glycol, propylparaben, purified water, saccharin sodium, sodium hydroxide, sorbitol solution, sucralose, xanthan gum

QUESTIONS OR COMMENTS?

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

PRINCIPAL DISPLAY PANEL

LEADER

NDC 70000-0629-1

Children's Multi-Symptom Cold

Dextromethorphan HBr

Guaifenesin

Phenylephrine HCl

Cough Suppressant

Expectorant

Nasal Decongestant

Very Berry Flavor

Ages 4+ Years

Relieves:

Stuffy Nose

Chest Congestion

Controls Cough

Breaks Up Mucus

COMPARE TO

CHILDREN'S MUCINEX®

MULTI-SYMPTOM COLD

active ingredients*

4FL OZ (118 mL)

No Coating Area

COATING FREE AREA

Glue

Drug Facts

Active ingredients (in each 5 mL): Purpose
Dextromethorphan HBr 5 mg... Cough suppressant
Guaifenesin 100 mg... Expectorant
Phenylephrine HCl 5.2 mg... Nasal decongestant

Uses

- helps lessen 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 influenza infection
 - 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, Parkinson's, or medical conditions, or Pseudoephedrine), 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
- parosmia or chronic cough such as occurs with asthma
- cough that occurs with too much phlegm (mucus)

When taking 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 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
- dose as shown or as directed by a doctor

Drug Facts (continued)

Age	Dose
children 8 years to under 12 years	10 mL every 4 hours
children 4 years to under 8 years	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 15-30°C (59-86°F)
- do not refrigerate
- dosing cup provided

Inactive ingredients: alpha acid styrene, DSC red #40, dextrose, diethyl stearate, FD&C blue #1, FD&C red #40, flavor, sucrose, methylparaben, potassium sorbate, propyl paraben, propylene glycol, polyethylene glycol, purified water, saccharin sodium, sodium hydroxide, sorbitol solution, sorbic acid, xanthan gum

Questions or comments?
call 800-445-9660 Mon-Fri 9:00 am to 4:00 pm est

KEEP BOX FOR COMPLETE INFORMATION

DO NOT USE IF SEAL AND/OR CAP IMPRINTED WITH "RECALLED FOR YOUR PROTECTION" IS BROKEN OR MISSING.

*This product is not manufactured or distributed by Cardinal Health, the distributor of Children's Mucinex® Multi-Symptom Cold.

LEADER²

Children's
Multi-Symptom Cold

Dextromethorphan HBr
Guaifenesin
Phenylephrine HCl
Cough Suppressant
Expectorant
Nasal Decongestant

LEADER²

Children's
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Dextromethorphan HBr
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Very Berry
Flavor

Ages 4+ Years

Relieves:
Stuffy Nose
Chest Congestion

Controls Cough
Breaks Up Mucus

COMPARE TO CHILDREN'S MUCINEX[®] MULTI-SYMPTOM COLD active ingredients*

100% Money Back Guarantee

4 FL OZ (118 mL)

LEADER²

Children's
Multi-Symptom Cold

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3030 QIP CSE
www.leader2.com
1-800-545-5455
Leader@le.com #le101

Cardinal Health

✓ LEADER² Brand Products Have A 100% Money Back Guarantee
Return to place of purchase if not satisfied.

No Coating Area



LOT: UNMANUFACTURED AREA TO BE LEFT BLANK FOR LOT & EXP. INFORMATION
EXP:

Drug Facts

Active Ingredients (in each 5 mL) Purpose
Dextromethorphan HBr 5 mg Cough suppressant
Guaifenesin 100 mg Expectorant
Phenylephrine HCl 2.5 mg Nasal decongestant

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

Warnings
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LEADER

NDC 70000-0629-4

Children's Multi-Symptom Cold

Dextromethorphan HBr | Guaifenesin
Phenylephrine HCl
Cough Suppressant | Expectorant
Nasal Decongestant

Very Berry
Flavor

Ages 4+ Years

Relieves:
24h's Nose
Throat Congestion
Cough
Phlegm & Mucus

100% Money Back Guarantee

4 FL OZ (118 mL)

Drug Facts (continued)

When using this product ■ do not use more than directed

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

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: potassium 5 mg, sodium 5 mg ■ store between 15-30°C (59-86°F)
■ do not refrigerate ■ dosing cup provided

DO NOT USE IF SEAL UNDER CAP IMPRINTED WITH "SEALED FOR YOUR PROTECTION" IS BROKEN OR MISSING.
Refer to carton for full labeling information

DEL. BY CAROLINA, OR 4300
www.leader.com 1-800-208-5285
WOODS CROSS HEALTH, LEADER, and LOGO are trademarks of Cardinal Health.

LOT: _____
EXP: _____

LEADER CHILDRENS MULTI SYMPTOM COLD

dextromethorphan hbr, guaifenesin, phenylephrine hcl liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0629
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
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
DEXTROSE (UNII: IY9XDZ35W2)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
PROPYL GALLATE (UNII: 8D45NN7V92)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM ANHYDROUS (UNII: I4807BK602)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	RED	Score	
Shape		Size	
Flavor	BERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0629-1	1 in 1 CARTON	03/15/2023	
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
OTC MONOGRAPH FINAL	part341	03/15/2023	

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

Establishment

Name	Address	ID/FEI	Business Operations
Guardian Drug Company		119210276	MANUFACTURE(70000-0629)

Revised: 3/2023

CARDINAL HEALTH 110, LLC. DBA LEADER