LEADER MAXIMUM STRENGTH MUCUS RELIEF DM- 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 Maximum Strength Mucus Relief DM

ACTIVE INGREDIENTS (in each 20 mL)

Dextromethorphan HBr, 20 mg

Guaifenesin, 400 mg

PURPOSE

Cough Suppressant

Expectorant

USE(S)

- 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 you get to sleep

WARNINGS

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DO NOT USE

- for children under 12 years of age
- if you are now 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 prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

ASK A DOCTOR BEFORE USE IF

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

WHEN USING THIS PRODUCT

do not use more than directed

STOP USE AND ASK 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.

IF PREGNANT OR BREAST-FEEDING

ask a health professional before use.

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
- dose as follows or as directed by a doctor
- **Adults & children 12 years & older:** 20 mL every 4 hours
- **Children under 12 years of age:** Do not use

OTHER INFORMATION

- each 20 mL contains: potassium 20 mg, sodium 20 mg
- store between 15-30°C (59-86°F)
- do not refrigerate
- dosing cup provided

INACTIVE INGREDIENTS

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

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

LEADER™
NDC 70000-0465-1

Maximum Strength
Mucus
Relief DM

Dextromethorphan HBr, 20 mg
Guaifenesin, 400 mg

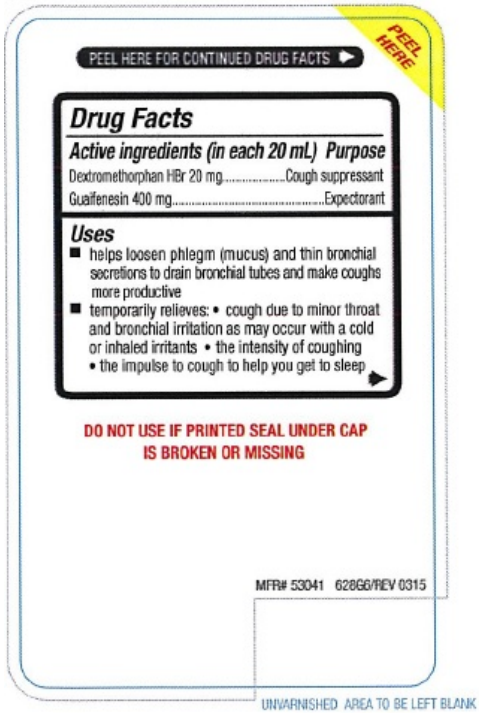
Cough Suppressant / Expectorant

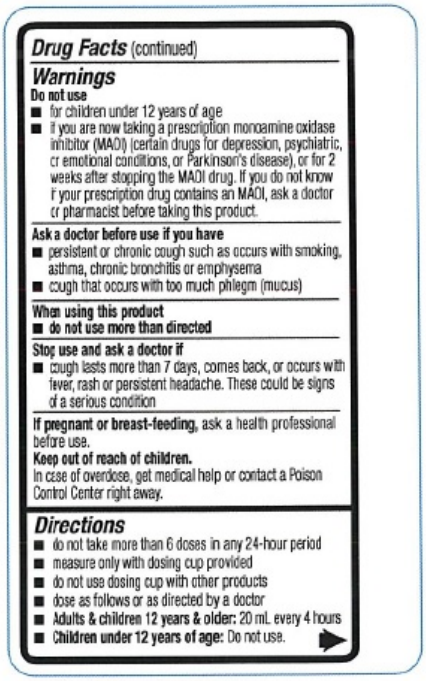
For Ages 12 & Over
Multi-Symptom

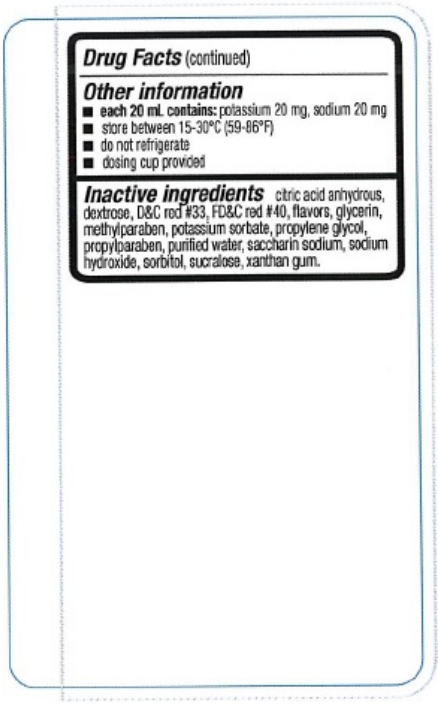
Relieves Chest Congestion
Controls Cough

Thins and loosens Mucus

COMPARE TO MUCINEX FAST MAX DM MAX active ingredients*
6 FL OZ (177 mL)







LEADER MAXIMUM STRENGTH MUCUS RELIEF DM

dextromethorphan hbr, guaifenesin liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70000-0465
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 20 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg in 20 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2)	
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)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SORBITOL (UNII: 506T60A25R)	
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:70000-0465-1	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/23/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	07/23/2019	

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

Revised: 1/2022

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