

**MUCUS RELIEF DM COUGH MAXIMUM STRENGTH- dextromethorphan hbr and guaifenesin tablet, film coated**  
**Cardinal Health 110, LLC. DBA Leader**

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**Leader 44-533**

***Active ingredients (in each immediate-release tablet)***

Dextromethorphan HBr 20 mg  
Guaifenesin 400 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 associated with the common cold
  - the intensity of coughing
  - the impulse to cough to help you get to sleep

***Warnings***

**Do not use**

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 you have**

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

**When using this product**

**do not exceed recommended dosage.**

**Stop use and ask a doctor if**

cough persists more than 7 days, tends to recur, or is accompanied by a 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***

- take with a full glass of water
- adults and children 12 years and over: 1 tablet every 4 hours. Do not take more than 6 tablets in 24 hours.
- children under 12 years: do not use

***Other information***

- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- see end flap for expiration date and lot number
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)

***Inactive ingredients***

D&C yellow #10 aluminum lake, hypromellose, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, povidone, silicon dioxide, sodium starch glycolate, stearic acid

***Questions or comments?***

**1-800-426-9391**

***Principal display panel***

**LEADER™**

NDC 70000-0278-1

Maximum Strength

**Mucus Relief**

**DM Cough**

Dextromethorphan HBr, 20 mg † Guaifenesin, 400 mg  
Cough Suppressant † Expectorant

Controls Cough

Thins and Loosens Mucus

Immediate-Release  
Tablets

**24 TABLETS**

ACTUAL SIZE

100% Money Back Guarantee

**TAMPER EVIDENT: DO NOT USE IF  
PACKAGE IS OPENED OR IF BLISTER  
UNIT IS TORN, BROKEN OR SHOWS  
ANY SIGNS OF TAMPERING**

50844 REV0118A53308

**Cardinal**Health™

DISTRIBUTED BY CARDINAL HEALTH

DUBLIN, OHIO 43017

[www.myleader.com](http://www.myleader.com) 1-800-200-6313

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Cardinal Health.

√ All LEADER™ Brand Products Have A

**100% Money Back Guarantee**

Return to place of purchase if not satisfied.

**PARENTS:**

Learn about teen medicine abuse

[www.StopMedicineAbuse.org](http://www.StopMedicineAbuse.org)



Leader 44-533

## MUCUS RELIEF DM COUGH MAXIMUM STRENGTH

dextromethorphan hbr and guaifenesin tablet, film coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70000-0278
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII: 7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>D&amp;C YELLOW NO. 10 ALUMINUM LAKE</b> (UNII: CQ3XH3DET6)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6130)	
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	

<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>SODIUM STARCH GLYCOLATE TYPE A POTATO</b> (UNII: 5856J3G2A2)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	

### Product Characteristics

<b>Color</b>	yellow	<b>Score</b>	2 pieces
<b>Shape</b>	OVAL	<b>Size</b>	16mm
<b>Flavor</b>		<b>Imprint Code</b>	44;533
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0278-1	2 in 1 CARTON	12/31/2005	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:70000-0278-2	1 in 1 CARTON	12/31/2005	12/04/2022
2		50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	12/31/2005	

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

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(70000-0278)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(70000-0278) , pack(70000-0278)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(70000-0278)

### Establishment

Name	Address	ID/FEI	Business Operations
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LNK International, Inc.		967626305	pack(70000-0278)
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## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(70000-0278)

Revised: 5/2024

Cardinal Health 110, LLC. DBA Leader