

**GUAIFENESIN D- guaifenesin and pseudoephedrine hydrochloride tablet, extended release**  
**CARDINAL HEALTH 110, LLC. DBA LEADER**

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**Mucus Relief D**

***Drug Facts***

<b><i>Active ingredients (in each extended-release tablet)</i></b>	<b><i>Purposes</i></b>
Guaifenesin 600 mg	Expectorant
Pseudoephedrine HCl 60 mg	Nasal Decongestant

**Uses**

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
- temporarily relieves nasal congestion due to:
  - common cold
  - hay fever
  - upper respiratory allergies
- temporarily restores freer breathing through the nose
- promotes nasal and/or sinus drainage
- temporarily relieves sinus congestion and pressure

**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**

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- cough accompanied by too much phlegm (mucus)

**When using this product**

- do not use more than directed

**Stop use and ask a doctor if**

- you get nervous, dizzy, or sleepless
- symptoms do not get better within 7 days, come back or occur with a fever, rash, or persistent headache. These could be signs of a serious illness.

**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 (1-800-222-1222).

### **Directions**

- do not crush, chew, or break extended-release tablet
- take with a full glass of water
- this product can be administered without regard for timing of meals
- adults and children 12 years and older: 2 extended-release tablets every 12 hours; not more than 4 extended-release tablets in 24 hours
- children under 12 years of age: do not use

### **Other information**

- **Tamper evident: Do not use if carton is open or if printed seal on blister is broken or missing.**
- store between 20-25°C (68-77°F)

### **Inactive ingredients**

carbomer homopolymer, NF; hypromellose, USP; magnesium stearate, NF; microcrystalline cellulose, NF

### **Questions?**

call toll-free Monday to Friday 8:30 am to 5:00 pm EST at **1-800-406-7984**. You may also report side effects to this phone number.

DISTRIBUTED BY CARDINAL HEALTH, DUBLIN, OHIO 43017

### **PRINCIPAL DISPLAY PANEL - 36 Tablet Blister Pack Carton**

LEADER™

NDC 70000-0580-2

Mucus

Relief D

Guaifenesin, 600 mg

Pseudoephedrine Hydrochloride, 60 mg

Extended-Release Tablets

Expectorant | Nasal Decongestant

12-Hour

Clears Nasal/Sinus Congestion  
Thins and Loosens Mucus  
Immediate and Extended Release

Actual Size

36  
EXTENDED-RELEASE  
TABLETS

COMPARE TO  
MUCINEX® D  
active ingredients†

100% Money  
Back Guarantee

LEADER<sup>TM</sup>

# Mucus Relief D

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Expectorant | Nasal Decongestant

LEADER<sup>TM</sup>

NDC 70000-0580-2

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Thins and Loosens Mucus  
Immediate and Extended Release



Actual Size

36 EXTENDED-RELEASE TABLETS

COMPARE TO  
MUCINEX<sup>®</sup> D  
active ingredients<sup>†</sup>

100% Money  
Back Guarantee

# Mucus Relief D

Guaifenesin, 600 mg  
Pseudoephedrine Hydrochloride, 60 mg  
Extended-Release Tablets  
Expectorant | Nasal Decongestant

Unique Bi-Layer Tablet

Immediate-Release Layer



Extended-Release Layer

Tablet shown actual size

Lot No.

Expiration Date:

NON VARNISH

NON PATENTI



5221403

LEADER™

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**Keep the carton.**

**It contains important information. See end panel for expiration date.**

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DISTRIBUTED BY CARDINAL HEALTH, DUBLIN, OHIO 43017  
www.myleader.com 1-800-200-6313

**100% Money Back Guarantee**  
Return to place of purchase if not satisfied.

CIN 5730098 REV. 8/21



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GLUE - NO COATING



## GUAIFENESIN D

guaifenesin and pseudoephedrine hydrochloride tablet, extended release

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70000-0580
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Guaifenesin</b> (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)	Guaifenesin	600 mg
<b>Pseudoephedrine Hydrochloride</b> (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	Pseudoephedrine Hydrochloride	60 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED)</b> (UNII: HHT01ZNK31)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	

### Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	16mm
<b>Flavor</b>		<b>Imprint Code</b>	058
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0580-1	1 in 1 CARTON	05/06/2021	
1		18 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:70000-0580-2	2 in 1 CARTON	05/06/2021	
		18 in 1 BLISTER PACK; Type 0: Not a Combination Product		

2

18 in 1 BLISTER PACK; Type U: Not a Combination Product

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA212542	05/06/2021	

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

### Establishment

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		184769029	MANUFACTURE(70000-0580)

Revised: 5/2022

CARDINAL HEALTH 110, LLC. DBA LEADER