

**LEADER MUCUS RELIEF COLD FLU AND SORE THROAT- acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl tablet, film coated**  
**Cardinal Health**

*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.*

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**Cardinal Health Mucus Relief Cold, Flu & Sore Throat Drug Facts**

**Active ingredients (in each caplet)**

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Guaifenesin 200 mg

Phenylephrine HCl 5 mg

**Purpose**

Pain reliever/fever reducer

Cough suppressant

Expectorant

Nasal decongestant

**Uses**

- temporarily relieves these common cold and flu symptoms:
- nasal congestion
- cough
- minor aches and pains
- sore throat
- headache
- temporarily reduces fever
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive

**Warnings**

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters

- rash

If a skin reaction occurs, stop use and seek medical help right away.

Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

### **Do not use**

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- 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.
- if you have ever had an allergic reaction to this product or any of its ingredients

### **Ask a doctor before use if you have**

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

### **Ask a doctor or pharmacist before use if you are**

taking the blood thinning drug warfarin

### **When using this product**

do not use more than directed

### **Stop use and ask a doctor if**

- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion or cough gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back or occurs with 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.**

Overdose warning: In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

### **Directions**

- do not take more than directed (see overdose warning)
- do not take more than 10 caplets in any 24-hour period
- adults and children 12 years and older: take 2 caplets every 4 hours
- children under 12 years of age: do not use

### **Other information**

- each caplet contains: sodium 4 mg
- do not use if blister unit is broken or torn
- store at 20-25°C (68-77°F)

### **Inactive Ingredients**

croscarmellose sodium, crospovidone, FD&C blue #1 aluminum lake, FD&C blue #2 aluminum lake, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, silicon dioxide, stearic acid, talc, titanium dioxide

### **Questions or comments?**

1-800-719-9260

### **Package/Label Principal Display Panel**

Maximum Strength

Mucus Relief

Cold, Flu & Sore Throat

Acetaminophen | Dextromethorphan HBr

Guaifenesin | Phenylephrine HCl

Pain Reliever / Fever Reducer | Cough Suppressant

Expectorant | Nasal Decongestant

Relieves Headache, Fever & Sore Throat

COMPARE TO MUCINEX® FAST-MAX® COLD, FLU & SORE THROAT active ingredients

Controls Cough

Relieves Nasal & Chest Congestion

Things & Loosens Mucus

For Ages 12+

100% Money Back Guarantee

20 CAPLETS

LEADER<sup>TM</sup>

NDC 70000-0284-1

**Maximum Strength\*\***

# Mucus Relief

## Cold, Flu & Sore Throat

Acetaminophen | Dextromethorphan HBr  
Guaifenesin | Phenylephrine HCl

Pain Reliever / Fever Reducer | Cough Suppressant  
Expectorant | Nasal Decongestant

Relieves Headache,  
Fever & Sore Throat  
Controls Cough  
Relieves Nasal & Chest  
Congestion  
Thins & Loosens Mucus

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COMPARE TO  
MUCINEX<sup>®</sup>FAST-MAX<sup>®</sup>  
COLD, FLU &  
SORE THROAT  
active ingredients\*

100% Money  
Back Guarantee

: 381C9 E9 SF3

**100% Money Back Guarantee**  
Return to place of purchase.

**PARENTS:**  
Learn about teen medicine abuse  
[www.StopMedicineAbuse.org](http://www.StopMedicineAbuse.org)

\*\*Per 4-hour dose, dose every 4 hours  
Keep outer package for complete product information.  
Lift here to open

**CODE AREA**

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Essential to Care™ since 1979

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Gluten Free

CIN 5326558 REV. 6/17



**Drug Facts**

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Dextromethorphan HBr 10 mg.....	Cough suppressant
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**Uses** ■ temporarily relieves these common cold and flu symptoms: ■ nasal congestion  
■ cough ■ minor aches and pains  
■ sore throat ■ headache  
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■ liver disease ■ heart disease ■ diabetes ▶

**Drug Facts (continued)**

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

**Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin**

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**Questions or comments? 1-800-719-9260**

# LEADER MUCUS RELIEF COLD FLU AND SORE THROAT

acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl tablet, film coated

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70000-0284
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
CROSPVIDONE (15 MPAS AT 5%) (UNII: 68401960MK)	
MALTO DEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
POVIDONE (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

## Product Characteristics

<b>Color</b>	BLUE	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	20mm
<b>Flavor</b>		<b>Imprint Code</b>	L922
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0284-1	10 in 1 CARTON	07/06/2017	
1		2 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:70000-0284-2	15 in 1 CARTON	10/13/2017	
2		2 in 1 BLISTER PACK; 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	07/06/2017	

**Labeler** - Cardinal Health (097537435)

Revised: 1/2019

Cardinal Health