

**HEAD CONGESTION AND MUCUS- acetaminophen, guaifenesin, phenylephrine  
hcl tablet, film coated  
Cardinal Health 110, LLC. DBA Leader**

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**Leader 44-527C-SS**

***Active ingredients (in each caplet)***

Acetaminophen 325 mg  
Guaifenesin 200 mg  
Phenylephrine HCl 5 mg

***Purpose***

Pain reliever/fever reducer  
Expectorant  
Nasal decongestant

***Uses***

- temporarily relieves these symptoms associated with hay fever or other respiratory allergies, and the common cold:
  - headache
  - nasal congestion
  - minor aches and pains
  - sinus congestion and pressure
- temporarily reduces fever
- helps loosen phlegm (mucus) and thin bronchial secretions to 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:

- blisters
- rash
- skin reddening

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

**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**

- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- high blood pressure
- heart disease
- diabetes
- thyroid disease
- liver disease
- difficulty in urination due to enlargement of the prostate gland
- 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 exceed recommended dosage.**

### **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 headache that lasts. 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. Prompt 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**
- adults and children 12 years and over

- take 2 caplets every 4 hours
- swallow whole - do not crush, chew, or dissolve
- do not take more than 10 caplets in 24 hours
- children under 12 years: ask a doctor

### ***Other information***

- **each caplet contains:** sodium 3 mg
- see end flap for expiration date and lot number
- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)

### ***Inactive ingredients***

corn starch, crospovidone, flavor, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, sucralose, talc, titanium dioxide

### ***Questions or comments?***

**1-800-426-9391**

### ***Principal display panel***

**LEADER™**

NDC 70000-0083-1

Non-Drowsy

**Head Congestion  
& Mucus**

**Acetaminophen** | Guaifenesin | Phenylephrine HCl

Pain Reliever / Fever Reducer | Expectorant | Nasal Decongestant

Relieves:

Sinus Pressure

Headache

Chest Congestion

**COMPARE TO  
SUDAFED PE® HEAD  
CONGESTION + MUCUS**

active ingredients\*

100% Money Back Guarantee

**24 Caplets**

Actual Size

**TAMPER EVIDENT: DO NOT USE IF PACKAGE**

**IS OPENED OR IF BLISTER UNIT IS TORN,  
BROKEN OR SHOWS ANY SIGNS OF TAMPERING**

\*This product is not manufactured or distributed by Kenvue Inc., owner of the registered trademark SUDAFED PE® HEAD CONGESTION + MUCUS.

50844 REV0922B52708

100%

Money Back

Guarantee

Return to place of purchase

DISTRIBUTED BY CARDINAL HEALTH, DUBLIN, OHIO 43017

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

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**LEADER**<sup>TM</sup>

NDC 700000-0083-1

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Pain Reliever / Fever Reducer | Expectorant | Nasal Decongestant

Relieves:  
Sinus Pressure  
Headache  
Chest Congestion

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DISTRIBUTED BY CARDINAL HEALTH, DUBLIN, OHIO 43007  
www.myleader.com 1-800-200-535

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8-0225-527C-08-SSR  
REV0922852708

### Drug Facts (continued)

**Inactive ingredients** corn starch, crospovidone, flavor, magnesium stearate, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, sucralose, talc, titanium dioxide

### Drug Facts (continued)

Questions or comments? 1-800-426-9391

### Drug Facts (continued)

■ helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive

**Warnings:** 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: ■ blisters ■ rash ■ skin reddening

**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** ■ heart disease ■ emphysema ■ persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or thyroid disease ■ high blood pressure ■ diabetes ■ liver disease

### Drug Facts (continued)

**Difficulty in urination** due to enlargement of the prostate gland or 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 exceed recommended dosage.**

**Stop use and ask a doctor if** ■ nervousness, dizziness, or sleepiness occur

■ 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 headache that lasts. 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. Prompt 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 ■ adults and children 12 years and over ■ take 2 caplets every 4 hours ■ swallow whole - do not crush, chew, or dissolve ■ do not take more than 10 caplets in 24 hours ■ children under 12 years: ask a doctor

**Other information** ■ each caplet contains: sodium 3 mg ■ see end flap for expiration date and lot number

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

no print / no varnish area  
lot no. & exp. date

CIN 5689494 REV. 2/23  
0 96295 14061 3

Leader 44-527C

## HEAD CONGESTION AND MUCUS

acetaminophen, guaifenesin, phenylephrine hcl tablet, film coated

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70000-0083
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>CROSPVIDONE, UNSPECIFIED</b> (UNII: 2S7830E561)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POLYVINYL ALCOHOL, UNSPECIFIED</b> (UNII: 532B59J990)	
<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)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

## Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	19mm
<b>Flavor</b>	MENTHOL	<b>Imprint Code</b>	44;527
<b>Contains</b>			

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:70000-0083-1	2 in 1 CARTON	03/11/2021	
1		12 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 Drug	M012	03/11/2021	

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

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(70000-0083) , pack(70000-0083)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(70000-0083)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(70000-0083)

Revised: 7/2025

Cardinal Health 110, LLC. DBA Leader