

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

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 1-800-200-6313

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Drug Facts (continued)

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

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■ with other drugs containing acetaminophen

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■ fever gets worse or lasts more than 3 days

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When using this product do not exceed recommended dosage.

drug warfarin.

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

■ difficulty in urination due to enlargement of the prostate gland

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Drug Facts (continued)

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Drug Facts (continued)

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

Drug Facts (continued)

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Leader 44-527C

HEAD CONGESTION AND MUCUS

acetaminophen, guaifenesin, phenylephrine hcl tablet, film coated

Product Information				
Product Type		HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0083
Route of Administration		ORAL		
Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)			ACETAMINOPHEN	325 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)			GUAIFENESIN	200 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)			PHENYLEPHRINE HYDROCHLORIDE	5 mg
Inactive Ingredients				
Ingredient Name				Strength
STARCH, CORN (UNII: O8232NY3SJ)				
CROSPVIDONE, UNSPECIFIED (UNII: 2S7830E561)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
MALTODEXTRIN (UNII: 7CVR7L4A2D)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)				
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
SUCRALOSE (UNII: 96K6UQ3ZD4)				
TALC (UNII: 7SEV7J4R1U)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
Product Characteristics				
Color	white	Score	no score	
Shape	OVAL	Size	19mm	
Flavor	MENTHOL	Imprint Code	44;527	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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)