MUCUS RELIEF PE SINUS CONGESTION- guaifenesin, phenylephrine hcl tablet, film coated

Cardinal Health 110, LLC. DBA Leader

Leader 44-542

Active ingredients (in each immediate-release tablet)

Guaifenesin 400 mg Phenylephrine HCl 10 mg

Purpose

Expectorant 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 the common cold, hay fever or other upper respiratory allergies
- 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
- difficulty in urination due to enlargement of the prostate gland
- 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

- nervousness, dizziness, or sleeplessness occur
- symptoms do not improve within 7 days or are accompanied by fever
- 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

- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

Inactive ingredients

hypromellose, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, povidone, silicon dioxide, sodium starch glycolate, stearic acid

Ouestions or comments?

1-800-426-9391

Principal Display Panel

NDC 70000-0141-1

LEADER™

Mucus Relief PE Sinus Congestion

Guaifenesin, 400 mg | Phenylephrine HCl, 10 mg Expectorant | Nasal Decongestant

Relieves Nasal / Sinus Congestion Thins and Loosens Mucus Alleviates Chest Congestion

Immediate-Release

Actual Size

100% Money Back Guarantee

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

CardinalHealth™

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

Essential to Care™ since 1979

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ALL LEADER™ Brand Products Have A

100% Money Back Guarantee

Return to place of purchase if not satisfied.

50844 REV0118A54215



MUCUS RELIEF PE SINUS CONGESTION

guaifenesin, phenylephrine hcl tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0141
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg		
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg		

Inactive Ingredients					
Ingredient Name	Strength				
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)					
MAGNESIUM STEARATE (UNII: 70097M6I30)					
MALTODEXTRIN (UNII: 7CVR7L4A2D)					
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)					
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)					
POVIDONE, UNSPECIFIED (UNII: FZ 989GH94E)					
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)					
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)					
STEARIC ACID (UNII: 4ELV7Z65AP)					

Product Characteristics				
Color	white	Score	no score	
Shape	OVAL	Size	16mm	
Flavor		Imprint Code	44;542	
Contains				

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000- 0141-1	1 in 1 CARTON	04/15/2006	
1		50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing In	formation		
Marketing	Application Number or Monograph	Marketing Start	Marketing End

Category	Citation	Date	Date
OTC Monograph Drug	M012	04/15/2006	

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

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(70000-0141)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	pack(70000-0141)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(70000-0141)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	pack(70000-0141)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(70000-0141)

Revised: 3/2024 Cardinal Health 110, LLC. DBA Leader