

LEADER CHEST CONGESTION RELIEF G450- guaifenesin tablet

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.

Drug Facts

Active ingredient (per tablet)

Guaifenesin 400mg

Purpose

Expectorant

Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus
- helps make coughs more productive

Warnings

Ask doctor before use if you have

- persistent or chronic cough, such as occurs with smoking, asthma, bronchitis or emphysema
- cough is accompanied by excessive phlegm (mucus)

Stop use and ask doctor if

- Symptoms are accompanied by fever, rash or persistent headache
- cough persists for more than 1 week or tends to recur

A persistent cough may be a sign 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 immediately.

Directions

- **Adults and children 12 years of age and over:** take 1 tablet every 4 hours as needed
- **Children 6 to 10 under 12 years of age:** take 1/2 tablet every 4 hours as needed
- **Children under 6 years of age:** consult a doctor

Do not exceed 6 doses in a 24 hour period or as directed by a doctor

Other Information

store at 15°-30°C (59°-86°F)

Inactive ingredients

magnesium stearate, microcrystalline cellulose. May also contain (colloidal) silicon dioxide, (co) povidone, dicalcium phosphate, maltodextrin, sodium starch glycolate, stearic acid.

LEADER²

Chest Congestion Relief
Guaifenesin, 400 mg | Expectorant

NDC 70000-0055-1

LEADER²

Chest Congestion Relief
Guaifenesin, 400 mg | Expectorant

Makes Coughs More Productive
Loosens & Relieves Chest Congestion
Dye-Free
Immediate-Release Tablets

60 TABLETS

100% Money Back Guarantee

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Caution: do not use if imprinted seal under cap is broken or missing

Drug Facts

Active ingredient (in each tablet)	Purpose
Guaifenesin 400mg	Expectorant

Uses ■ helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus
■ helps make coughs more productive

Warnings
Ask a doctor before use if you have ■ persistent or chronic cough, such as occurs with smoking, asthma, chronic bronchitis or emphysema
■ cough is accompanied by excessive phlegm (mucus)
Stop use and ask a doctor if ■ cough persists for more than 1 week or tends to recur. **A persistent cough may be a sign of a serious condition.**
■ symptoms are accompanied by fever, rash or persistent headache

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 Poison Control at 800-222-1222 immediately.

Directions

For adults and children 12 years and older	take 1 tablet every 4 hours as needed. Do not exceed 6 tablets in 24 hours
For children 6 to under 12 years	take 1/2 tablet every 4 hours as needed. Do not exceed 3 tablets in 24 hours
For children under 6 years	consult a doctor

Other information store at room temperature 15°-30°C (59°-86°F)

Inactive ingredients magnesium stearate, maltodextrin, microcrystalline cellulose, povidone K30, povidone 90F, silicon dioxide, stearic acid

Questions or comments? 1-800-321-7178

GUAFORLDR REV 8/20

DISTRIBUTED BY CARDINAL HEALTH, DUBLIN, OHIO 43007
www.myleader.com 1-800-200-6333

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

CIN 5559958 REV. 8/20

FPO

0 96295 14009 5

**No Varnish in this area
DO NOT PRINT BOX**

**No Intervening materials
between ingredient
statement and name and
place of business (AEA
distributed by statement).**

LEADER CHEST CONGESTION RELIEF G450

guaifenesin tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0055
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Guaifenesin (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)	Guaifenesin	400 mg

Inactive Ingredients

Ingredient Name	Strength
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
COPOVIDONE (UNII: D9C330MD8B)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

Product Characteristics

Color	white	Score	2 pieces
Shape	OVAL	Size	17mm
Flavor		Imprint Code	PH063
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0055-1	1 in 1 CARTON	09/01/2020	
1		60 in 1 BOTTLE, PLASTIC; 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	09/01/2020	

Labeler - Cardinal Health (063997360)

Registrant - Reese Pharmaceutical Co (004172052)

Establishment

Name	Address	ID/FEI	Business Operations
Pharbest		557054835	manufacture(70000-0055)

Revised: 12/2022

Cardinal Health