

MUCUS RELIEF- guaifenesin 400 mg tablet
Health Pharma USA LLC

Guaifenesin 400 mg Caplets

Active ingredient (in each tablet)

Guaifenesin 400 mg

Purpose

Expectorant

Uses

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

Warnings

ask a doctor before use if you have

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

When using this product

- do not exceed recommended dosage
- do not use for more than 7 days

Stop use and ask a doctor if

- cough lasts for more than 7 days, recurs, or is accompanied by 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:

- **adults and children 12 years of age and over:**take 1 tablet every 4 hours with a full glass of water while symptoms persist. Do not exceed 6 doses in 24 hours.
- **children under 12 years:**do not use

Other information

- each tablet contains: sodium 1.24 mg VERY LOW SODIUM
- store at 25°C (77°F) excursions between 15°-30°C (59°-86°F)
- keep in a dry place and do not expose to heat
- read all product information before using
- **TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING**

Inactive ingredients

colloidal silicon dioxide, magnesium stearate, microcrystalline cellulose, stearic acid, sodium starch glycolate

Questions or Comments

Call toll free 1-844-832-1138 Monday through Friday 9AM – 5PM EST or www.healthlifeofusa.com

Principal Display Panel***COMPARE TO ACTIVE INGREDIENT IN Guai-Aid® 400****

Guaifenesin 400 mg

Expectorant

* This product is not manufactured or distributed by Health Products Express, Inc., owner of the registered trademark Guai-Aid® 400.



Health Pharma USA LLC

1600 Hart Street, Rahway, NJ 07065
Phone: 732-540-8421

BULK LABEL _____ of _____

PRODUCT NAME: Guaifenesin 400 mg Caplets		
PRODUCT CODE # PC075	LOT #	Labeler code – 71679-075-00
NET WEIGHT (KG)	Caplets/BOX	
17.00	36,960	

WARNING: Keep out of Children. This bulk shipment is intended for further processing only. Repackage contents as soon as possible. This is a shipping container only and will not protect contents from damage by heat, cold and moisture indefinitely. Manufacturer will not accept responsibility for spoilage or violations of the food, Drug and cosmetic act due to prolonged storage in this container. Contents must be repackaged prior to resale and must be labeled in full compliance with the requirement of the Food, Drug and Cosmetic Act.

STORAGE: Store at a controlled room temperature 15-30°C (59-86° F)

MUCUS RELIEF			
guaifenesin 400 mg tablet			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71679-075
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)		
	SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
	MAGNESIUM STEARATE (UNII: 70097M6130)		
	CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)		
	STEARIC ACID (UNII: 4ELV7Z65AP)		
	POVIDONE (UNII: FZ989GH94E)		

Product Characteristics

Color	white	Score	no score
Shape	OVAL	Size	17mm
Flavor		Imprint Code	G400
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71679-075-00	1 in 1 BOX	04/13/2016	
1		36960 in 1 BAG; 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	04/13/2016	

Labeler - Health Pharma USA LLC (080804485)

Establishment

Name	Address	ID/FEI	Business Operations
Health Pharma USA LLC		080804485	manufacture(71679-075)

Revised: 10/2023

Health Pharma USA LLC