GUAIFENESIN- guaifenesin tablet
Health Pharma USA LLC

Guaifenesin Tablets, USP 400 mg

Active ingredient (in each caplet)

Guaifenesin 400 mg

Purpose

Expectorant

Uses

- Temporary symptomatic relief from congested chests and cough.

Warnings

A persistent cough may be a sign of a serious condition. If cough persists for more than 1 week, tends to recur, or is accompanied by a fever, rash, or persistent headache, consult a doctor.

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 consume alcohol, benzodiazepines or opioids.

Stop use and ask a doctor if

cough lasts for more than 7 days please consult your physician or healthcare provider.

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 (1-800-222-1222) right away.

Directions

- **Adults and children 12 years of age and over:**take 1 caplet a day.
- **Children under 12 years:**Do not use.
- Do not exceed 4 doses in 24 hours.

Other information

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

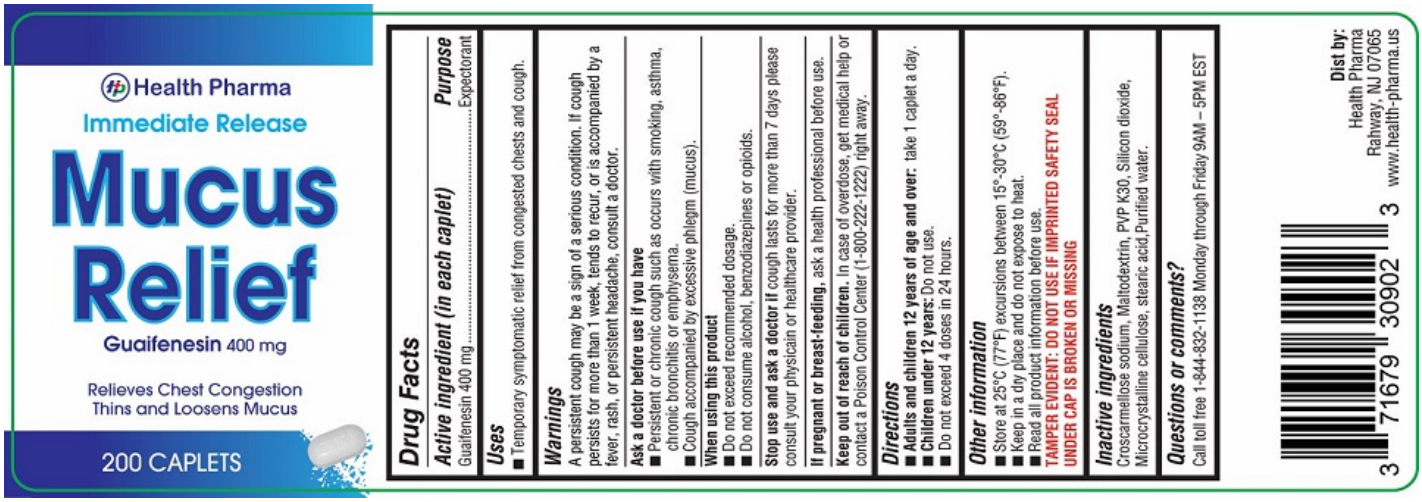
Inactive ingredients

Croscarmellose sodium, Maltodextrin, PVP K30, Silicon dioxide, Microcrystalline cellulose, stearic acid, Purified water.

Questions or comments?

Call toll free 1-844-832-1138 Monday through Friday 9AM – 5PM EST

PRINCIPAL DISPLAY PANEL



GUAIFENESIN TABLETS USP, 400 MG

Each uncoated tablet contains: Guaifenesin USP, 400 mg

Batch No.	:		**Mfg. Date**	:	
Shipper No.	:		**Exp. Date**	:	
Quantity	:	**38,500 Tablets**	**Repack Before Date**	:	
NDC No.	:	**71679-309-00**			

WARNING : KEEP OUT OF THE REACH OF CHILDREN

Store At USP Controlled Room Temperature of 59° to 86° F (15° C to 30° C). Protect from Light, Moisture and Freezing.

HANDLE WITH CARE

This is a Bulk Shipment Intended for Further Processing Only. Contents Should Be Approved, Repackaged Immediately (9 Months From MFG. Date) and Labelled in strict conformance with The FD&C Act and Regulations There under.

"G400" Debossed

Manufactured By:	***Manufactured For:***
ELYSIUM PHARMACEUTICALS LIMITED At & Post – Dabhasa, Tal.: Padra, Dist.: Vadodara, Gujarat – 391440, INDIA Manufacturer Code No.: GUJ/DRUGS/G/25/2258 Labeler Code #14803	**HEALTH PHARMA USA LLC** Labeler Code #71679 1600 Hart Street, Rahway, New Jersey (NJ) 07065, United States (USA)

CAUTION : "FOR MANUFACTURING, PROCESSING OR REPACKING"

S-056-00

GUAIFENESIN

guaifenesin tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71679-309

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)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
WATER (UNII: 059QF0KO0R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
POVIDONE K30 (UNII: U725QWY32X)	

Product Characteristics

Color	white	**Score**	no score
Shape	CAPSULE	**Size**	14mm
Flavor		**Imprint Code**	G400
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71679-309-00	38500 in 1 BOTTLE; Type 0: Not a Combination Product	03/07/2024	
2	NDC:71679-309-02	200 in 1 BOTTLE; Type 0: Not a Combination Product	02/07/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	02/07/2024	

Labeler - Health Pharma USA LLC (080804485)

Establishment

Name	Address	ID/FEI	Business Operations
Elysium Pharmaceuticals Ltd.		915664486	manufacture(71679-309) , analysis(71679-309)

Establishment

Name	Address	ID/FEI	Business Operations
HHH Pharmaceuticals		144848997	pack(71679-309)

Revised: 12/2025

Health Pharma USA LLC