

MUCUS RELIEF- guaifenesin tablet
SPIRIT PHARMACEUTICALS LLC

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.

ASSURED™ EXPECTORANT MUCUS RELIEF

Drug Facts

Active ingredient (in each caplet)

Guaifenesin 400 mg

Purpose

Expectorant

Uses

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

Warnings

Do not use

- for children under 12 years of age

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 too much phlegm (mucus)

Stop use and ask a doctor if

- cough lasts more than 7 days, comes back, or occurs with fever, rash, or persistent headache. These could be signs of a serious illness.

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. 1-800-222-1222

Directions

- do not crush, chew, or break caplet
- take with a full glass of water
- adults and children 12 years of age and over: take 1 caplet every 4 hours with a full glass of water while symptoms persist. Do not exceed 6 caplets in 24 hours.
- children under 12 years of age: do not use

Other information

- store between 20-25°C (68-77°F)

Inactive ingredients

Colloidal silicone dioxide, magnesium stearate, maltodextrin, microcrystalline cellulose, polyvinyl pyrrolidone, sodium starch glycolate, stearic acid

Questions or comments?

1-888-333-9792

**DISTRIBUTED BY
GREENBRIER INTERNATIONAL, INC.
500 VOLVO PARKWAY, CHESAPEAKE, VA 23320**

PRINCIPAL DISPLAY PANEL - 15 Caplet Bottle Carton

ASSURED™

EXPECTORANT

MUCUS

RELIEF

- **Guaifenesin 400 mg**

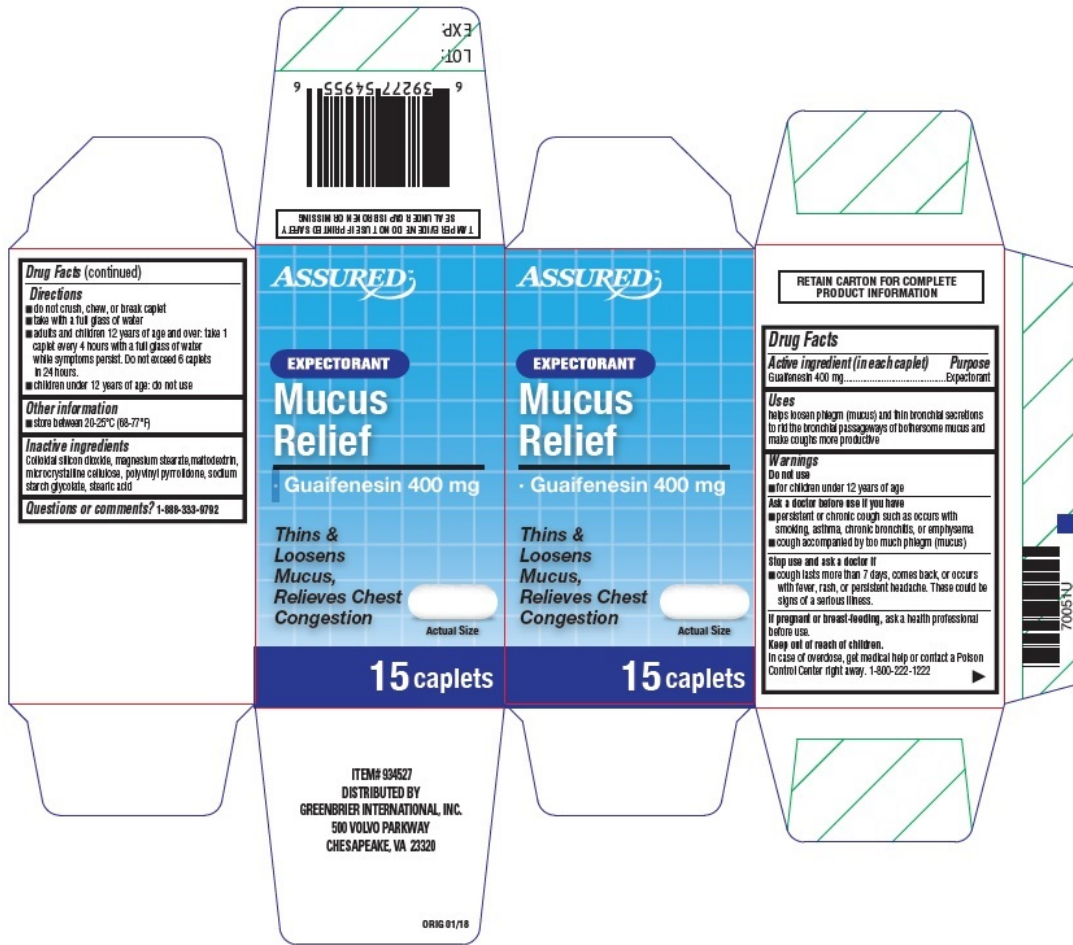
Thins &

Loosens

Mucus,

Relieves Chest Congestion

Actual Size



MUCUS RELIEF

guaifenesin tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68210-0116
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6B30)	
MALTO DEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POVIDONE K30 (UNII: U725QWY32X)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	white	Score	no score
Shape	CAPSULE	Size	17mm
Flavor		Imprint Code	EB
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-0116-1	1 in 1 CARTON	03/15/2018	
1		15 in 1 BOTTLE; 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	03/15/2018	

Labeler - SPIRIT PHARMACEUTICALS LLC (179621011)

Establishment

Name	Address	ID/FEI	Business Operations
ELYSIUM PHARMACEUTICALS LTD		915664486	manufacture(68210-0116)

Revised: 3/2018

SPIRIT PHARMACEUTICALS LLC