

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.

MUCUS RELIEF Caplets

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

PRINCIPAL DISPLAY PANEL

SOUNDBODY™

MUCUS

RELIEF

Guaifenesin 400 mg

Expectorant

Thins &

Loosens

Mucus,

Relieves Chest Congestion

60 Caplets



MUCUS RELIEF

guaifenesin tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68210-0611
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: 70097M6I30)				
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:68210-0611-6	1 in 1 CARTON	02/11/2020	
1		60 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	02/11/2020		

Labeler - SPIRIT PHARMACEUTICALS LLC (179621011)

Establishment

Name	Address	ID/FEI	Business Operations
ELYSIUM PHARMACEUTICALS LTD		915664486	manufacture(68210-0611)

Revised: 2/2020

SPIRIT PHARMACEUTICALS LLC