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

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

Questions or comments?

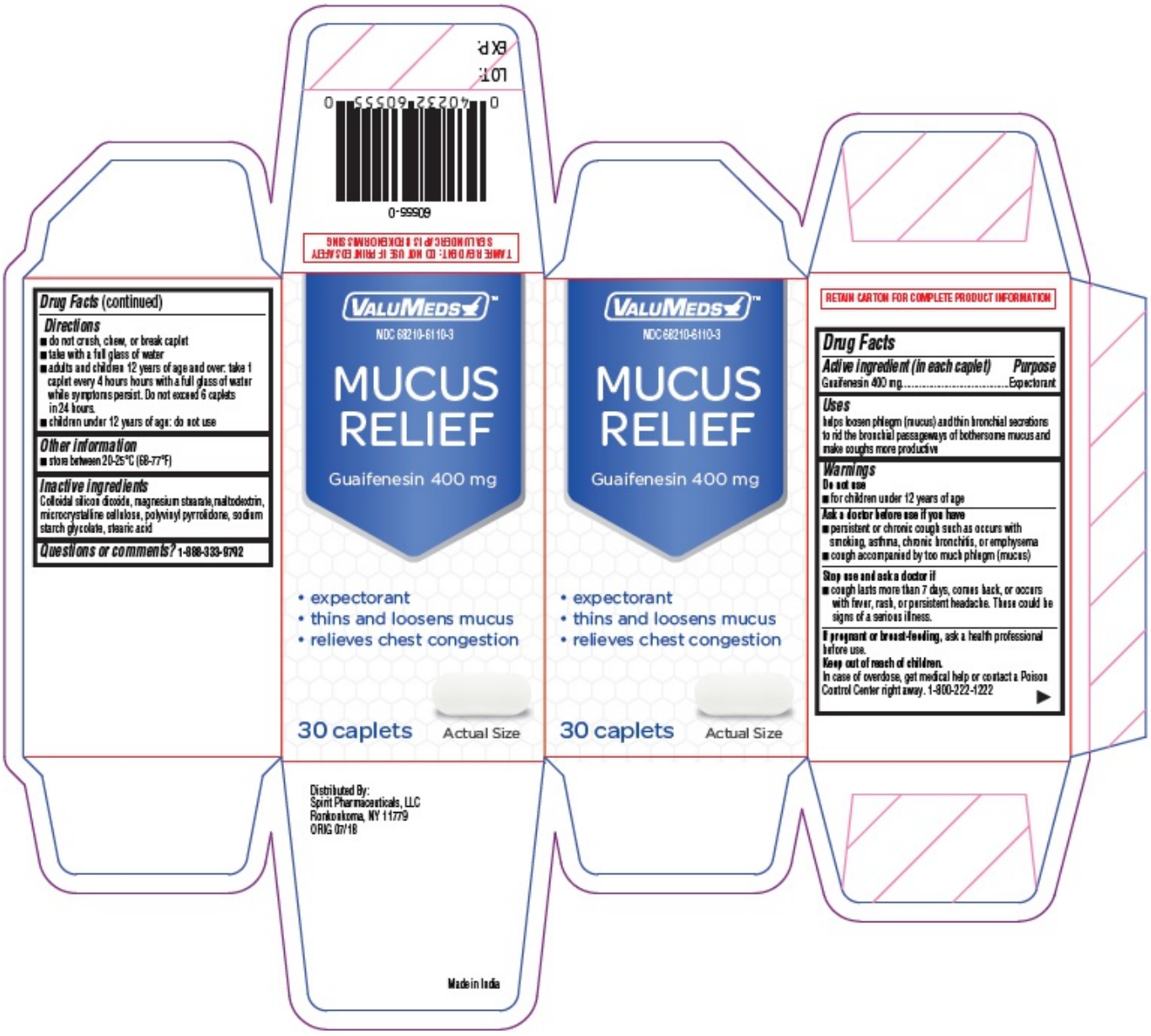
1-888-333-9792

PRINCIPAL DISPLAY PANEL

Mucus Relief

Guaifenesin 400mg

• Expectorant
• Thins and Loosens Mucus
• Relieves Chest Congestion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Questions or comments? 1-888-333-9792
TAMPER EVIDENT: DO NOT USE IF PRINT IS SMEARED OR SEAL UNDER CAP IS BROKEN OR MISSING
ValuMeds
NDC 68210-6110-3
MUCUS RELIEF
Guaifenesin 400 mg
• expectorant
• thins and loosens mucus
• relieves chest congestion
30 caplets
Actual Size
Distributed By:
Spirit Pharmaceuticals, LLC
Ronkonkoma, NY 11779
ORIG 07/18
Made in India
RETAIN CARTON FOR COMPLETE PRODUCT INFORMATION
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Active ingredient (in each caplet) Purpose
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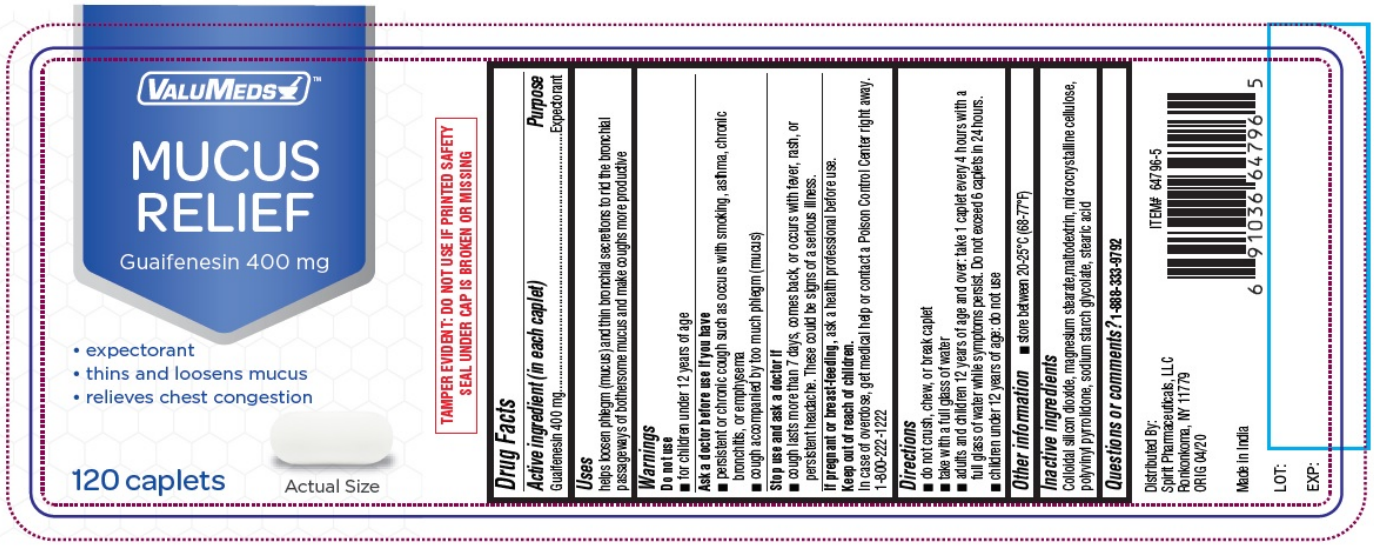
ValuMeds
MUCUS RELIEF
Guaifenesin 400 mg
• expectorant
• thins and loosens mucus
• relieves chest congestion
120 caplets
Actual Size
TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING
Drug Facts
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Inactive ingredients
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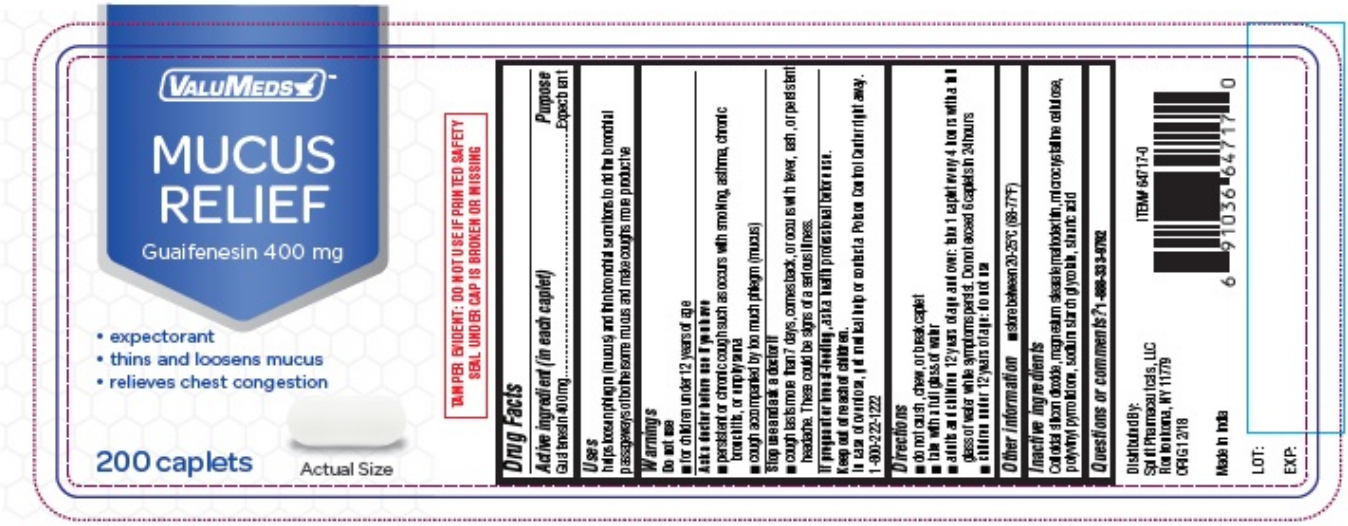
Questions or comments? 1-888-333-9792
ITEM# 64796-5
6 91036 64796 5
Distributed By:
Spirit Pharmaceuticals, LLC
Ronkonkoma, NY 11779
ORIG 04/20
Made in India
LOT:
EXP:



MUCUS RELIEF

guaifenesin tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68210-6110
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)	
MALTODEXTRIN (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:68210-6110-3	1 in 1 CARTON	03/10/2020	
1		30 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:68210-6110-2	200 in 1 PACKAGE; Type 0: Not a Combination Product	03/12/2020	
3	NDC:68210-6110-1	120 in 1 BOTTLE; Type 0: Not a Combination Product	04/06/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	03/10/2020	

Labeler - SPIRIT PHARMACEUTICALS LLC (179621011)

Establishment

Name	Address	ID/FEI	Business Operations
ELYSIUM PHARMACEUTICALS LIMITED		915664486	manufacture(68210-6110)

Revised: 4/2020 SPIRIT PHARMACEUTICALS LLC