

MUCUS RELIEF- guaifenesin 400 mg tablet
Richmond Pharmaceuticals, Inc.

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.

Guaifenesin Caplets, 400 mg

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 and make cough more productive

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)

KEEP OUT OF REACH OF CHILDREN

In case of overdose, get medical help or contact a Poison Control Center right away.

IN CASE OF PREGNANCY OR BREAST FEEDING SECTION

ask a health professional before use

stop use and ask a doctor

if cough lasts more than 7 days, comes back, or is accompanied by fever, rash or persistent headache. These could be signs of serious illness

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

- store at 15°-30°C (59°-86°F)
- **TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING**

Inactive ingredients

colloidal silicon dioxide, magnesium stearate, maltodextrin, microcrystalline cellulose, stearic acid,

sodium starch glycolate

Questions or Comments

call 804-270-4498, 8.30 am-4.30 pm ET, Monday - Friday

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

Guaifenesin 400 mg...Expectorant
NDC- 54738-981-30... 30 CAPLETS

NDC 54738-981-30

GUAIFENESIN

400 mg

Expectorant

30 CAPLETS

Richmond Pharmaceuticals, Inc.

Drug Facts	Active ingredient Purpose (in each caplet) Guaifenesin 400 mg Expectorant
Uses	helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
Warnings	Ask a doctor before use if you have <ul style="list-style-type: none">■ 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 is accompanied by fever, rash, or persistent headache. These could be signs of a serious illness.
Drug Facts (continued on back of label)	
TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING	
Distributed By: Richmond Pharmaceuticals, Inc. Richmond, VA 23233 USA	
LR1215	
0 54738 98130 8	
NO UV AREA	
PEEL HERE FOR MORE DRUG FACTS	

FRONT

Drug Facts (continued)
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 <ul style="list-style-type: none">■ do not take more than 6 doses in any 24-hour period■ this product is not intended for use in children under 12 years of age■ adults & children 12 years and over: 1 caplet every 4 hours■ children under 12 years: do not use
Other information <ul style="list-style-type: none">■ store at 15°-30°C (59°-86°F)
Inactive ingredients colloidal silicon dioxide, magnesium stearate, maltodextrin, microcrystalline cellulose, povidone, stearic acid
Questions or comments? call 804-270-4498, 8:30 am - 4:30 pm ET, Monday - Friday

NDC- 54738-981-60... 60 CAPLETS

NDC 54738-981-60

GUAIFENESIN

400 mg

Expectorant

60 CAPLETS

Richmond Pharmaceuticals, Inc.

Drug Facts	Active ingredient Purpose (in each caplet) Guaifenesin 400 mg Expectorant
Uses	helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
Warnings	<p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> ■ persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema ■ cough accompanied by too much phlegm (mucus) <p>Stop use and ask a doctor if cough lasts more than 7 days, comes back, or is accompanied by fever, rash, or persistent headache. These could be signs of a serious illness. →</p>

Drug Facts (continued on back of label)

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

Distributed By: Richmond Pharmaceuticals, Inc.
Richmond, VA 23233 USA

LR1215

0 54738 98160 5

PEEL HERE FOR DRUG FACTS

NO UV AREA

FRONT

Drug Facts (continued)

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

- do not take more than 6 doses in any 24-hour period
- this product is not intended for use in children under 12 years of age
- adults & children 12 years and over: 1 caplet every 4 hours
- children under 12 years: do not use

Other information

- store at 15°-30°C (59°-86°F)

Inactive ingredients

colloidal silicon dioxide, magnesium stearate, maltodextrin, microcrystalline cellulose, povidone, stearic acid

Questions or comments?

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MUCUS RELIEF

guaifenesin 400 mg tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54738-981
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)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
POVIDONE (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	white	Score	2 pieces
Shape	OVAL	Size	17mm
Flavor		Imprint Code	AP;152
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54738-981-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2016	
2	NDC:54738-981-60	60 in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	03/01/2016	

Labeler - Richmond Pharmaceuticals, Inc. (043569607)

Registrant - Advance Pharmaceutical Inc. (078301063)

Establishment

Name	Address	ID/FEI	Business Operations
Advance Pharmaceutical Inc.		078301063	manufacture(54738-981)

Revised: 10/2017

Richmond Pharmaceuticals, Inc.