

SAFREL MUCUS RELIEF- guaifenesin tablet, extended release
Safrel Pharmaceuticals, LLC.

Safrel Mucus Relief (Guaifenesin 600 mg) ER

Drug Facts

Active ingredient (in each extended-release tablet)

Guaifenesin 600 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 tablet
- take with a full glass of water
- this product can be administered without regard for the timing of meals
- adults and children 12 years of age and over: 1 or 2 tablets every 12 hours. Do not exceed 4 tablets in 24 hours.
- children under 12 years of age: do not use

Other information

- store between 20°-25°C (68°-77°F)

Inactive ingredients carbomer homopolymer type B, hypromellose, magnesium stearate, microcrystalline cellulose, sodium starch glycolate

Questions or comments?

Call **1-844-384-3723**

DO NOT USE IF PRINTED SEAL UNDER CAP IS BROKEN OR MISSING

Distributed by:

Safrel Pharmaceuticals, LLC

Bridgewater, NJ 08807

Made in India

Safrel Mucus Relief

Guaifenesin Extended-Release Tablets 600 mg

Expectorant

12 Hour

Relieves Chest Congestion

Thins and Loosens Mucus

Immediate and Extended Release

100 Extended-Release Tablets



Drug Facts
Active Ingredient (in each extended-release bi-layer tablet) Guaifenesin 600 mg.....Expectorant
Purpose
Uses ■ helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageway of bothersome mucus ■ helps make coughs more productive
Warnings Do not use ■ for children under 12 years 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 tablet ■ take with a full glass of water ■ this product can be administered without regard for the timing of meals ■ adults and children 12 years of age and over: 1 or 2 tablets every 12 hours. Do not exceed 4 tablets in 24 hours. ■ Children under 12 years of age: do not use
Other information ■ Tamper evident: Do not use if carton is open or if printed seal on blister is broken or missing. ■ store between 20-25°C (68-77°F)
Inactive ingredients carbomer homopolymer type B; hypromellose; magnesium stearate; microcrystalline cellulose; sodium starch glycolate
Questions or comments? Call 1-844-384-3723
DO NOT USE IF PRINTED SEAL UNDER CAP IS BROKEN OR MISSING
Distributed by: Safrel Pharmaceuticals, LLC Bridgewater, NJ 08807 www.safrel.com
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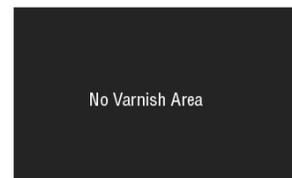
500 Extended-Release Tablets



Drug Facts
Active Ingredient (in each extended release tablet) Guaifenesin 600 mg.....Expectorant
Purpose
Uses ■ helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageway of bothersome mucus ■ helps make coughs more productive
Warnings Do not use ■ for children under 12 years 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 tablet ■ take with a full glass of water ■ this product can be administered without regard for the timing of meals ■ adults and children 12 years of age and over: 1 or 2 tablets every 12 hours. Do not exceed 4 tablets in 24 hours. ■ Children under 12 years of age: do not use
DO NOT USE IF PRINTED SEAL UNDER CAP IS BROKEN OR MISSING

Drug Facts (Continued)
Other Information ■ Tamper evident: Do not use if carton is open or if printed seal on blister is broken or missing. ■ store at 25°C (77°F); excursions permitted between 15-30°C (59-86°F)
Inactive Ingredients carbomer homopolymer type B; hypromellose; magnesium stearate; microcrystalline cellulose; sodium starch glycolate
Questions or comments? Call 1-844-384-3723

Distributed By: Safrel Pharmaceuticals
Bridgewater, NJ 08807 USA
www.safrel.com



SAFREL MUCUS RELIEF

guaifenesin tablet, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71309-460
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	600 mg

Inactive Ingredients

Ingredient Name	Strength
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL OR ALLYL SUCROSE CROSSLINKED) (UNII: K6MOM3T5YL)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I3O)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

Product Characteristics

Color	white	Score	no score
Shape	OVAL	Size	16mm
Flavor		Imprint Code	G;600
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71309-460-10	100 in 1 BOTTLE; Type 0: Not a Combination Product	02/21/2022	
2	NDC:71309-460-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	02/21/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA213420	02/21/2022	

Labeler - Safrel Pharmaceuticals, LLC. (080566287)

