

GUAIFENESIN- guaifenesin tablet, extended release
Safrel Pharmaceuticals, LLC.

Guaifenesin Extended-Release Tablets 1200mg

ACTIVE INGREDIENT(S)

Guaifenesin 1200 mg (for 1200 mg)

PURPOSE

Expectorant

USE(S)

- 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 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.

PREGNANCY/BREASTFEEDING

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 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 (For 600mg)
- adults and children 12 years of age and over: 1 tablet every 12 hours. Do not exceed 2 tablets in 24 hours. (For 1200mg)
- 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; hypromellos, magnesium stearate, microcrystalline cellulose, sodium starch glycolate

QUESTIONS OR COMMENTS

Contact 1-844-384-3723

Mon-Fri 8:00 AM EST to 5:00 PM PST.

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PRINCIPAL DISPLAY PANEL



<p>Drug Facts</p> <p>Active ingredient (in each extended-release bi-layer tablet) Guaifenesin 1200 mg.....Expectorant</p>	
<p>Uses</p> <ul style="list-style-type: none"> ■ helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageway of bothersome mucus ■ helps make coughs more productive 	<p>Purpose Expectorant</p>
<p>Warnings Do not use ■ for children under 12 years</p> <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 occurs with fever, rash, or persistent headache. These could be signs of a serious illness.</p> <p>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).</p>	
<p>Directions</p> <ul style="list-style-type: none"> ■ 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 tablet every 12 hours. Do not exceed 2 tablets in 24 hours. ■ Children under 12 years of age: do not use 	
<p>Other information</p> <ul style="list-style-type: none"> ■ 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) 	
<p>Inactive ingredients carbomer homopolymer type B; hypromellose; magnesium stearate; microcrystalline cellulose; sodium starch glycolate</p>	
<p>Questions or comments? Call 1-844-384-3723</p>	

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

Distributed by:
Safrel Pharmaceuticals, LLC
Bridgewater, NJ 08807
www.safrel.com



GUAIFENESIN

guaifenesin tablet, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71309-461
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	1200 mg

Inactive Ingredients

Ingredient Name	Strength
CARBOMER HOMOPOLYMER TYPE B (ALLYL SUCROSE CROSSLINKED) (UNII: Z135WT9208)	
HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

Product Characteristics

Color	white	Score	no score
Shape	OVAL (Elliptical)	Size	22mm
Flavor		Imprint Code	G;1200
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71309-461-56	56 in 1 BOTTLE; Type 0: Not a Combination Product	06/29/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA213420	12/18/2020	

Labeler - Safrel Pharmaceuticals, LLC. (080566287)