

MUCUS RELIEF- guaifenesin tablet, extended release
FSA STORE INC.

1203A-CRM-2023-0111

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)

■ retain carton for complete product information and warnings

Inactive ingredients

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

Questions or comments?

1-844-705-4384

PRINCIPAL DISPLAY PANEL

NDC 81522-203-02

caring mill™

†Compare to the active ingredient of Mucinex®

Mucus Relief

Guaifenesin Extended-Release Tablets 600 mg

Expectorant

12 Hour

Relieves Chest Congestion

Thins and Loosens Mucus

Immediate and Extended Release

Actual Size

20 EXTENDED-RELEASE TABLETS



MUCUS RELIEF

guaifenesin tablet, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81522-203
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
CARBOMER HOMOPOLYMER TYPE B (ALLYL SUCROSE CROSSLINKED) (UNII: Z135WT9208)	
HYPROMELLOSE 2910 (15 MPA.S) (UNII: 365FW2JZ0W)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
MAGNESIUM STEARATE (UNII: 70097M6130)	
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:81522-203-02	1 in 1 CARTON	01/11/2023	
1		20 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA213420	01/11/2023	

Labeler - FSA STORE INC. (049283340)

Revised: 1/2023

FSA STORE INC.