MUCUS RELIEF- guaifenesin tablet, extended release
AAA Pharmaceutical, Inc.

1203-RES-2024-0613

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 20-25ºC (68-77ºF)

■ 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

Restore U

NDC 57344-203-02

†COMPARE TO THE ACTIVE INGREDIENT IN MUCINEX®

12 HOUR

Mucus Relief

Guaifenesin Extended-Release Tablets, 600 mg

Expectorant

• Relieves Chest Congestion

• Thins & 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:57344-203
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: 36SFW2JZ0W)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
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:57344-203-02	2 in 1 CARTON	02/01/2024	
1		10 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	02/01/2024	

Labeler - AAA Pharmaceutical, Inc. (181192162)

Revised: 6/2024 AAA Pharmaceutical, Inc.