CARING MILL MUCUS ER- guaifenesin tablet, multilayer, extended release FSA Store Inc.

FSA Store Inc. Mucus-ER Drug Facts

Active ingredient (in each extended-release bi-layer caplet)

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 caplet
- 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 caplets every 12 hours. Do not exceed 4 caplets 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, FD&C blue #1 aluminum lake, hypromellose, magnesium stearate,

microcrystalline cellulose, sodium starch glycolate

Questions or comments?

1-800-719-9260

Package/Label Principal Display Panel

Compare to the active ingredient of Mucinex®

Mucus-ER

Guaifenesin Extended-Release Bi-Layer Tablets, 600 mg

Expectorant

12 Hour

- Relieves Chest Congestion
 - Thins and Loosens Mucus
- Immediate and Extended-Release

Actual Size

20 Extended-Release Bi-Layer Caplets*

*Capsule Shaped Tablets



CARING MILL MUCUS ER

quaifenesin tablet, multilayer, extended release

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81522-006	
Route of Administration	ORAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength Strength		
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W74	GUAIFENESIN 600 mg		

Inactive Ingredients	
Ingredient Name	Strength
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL OR ALLYL SUCROSE CROSSLINKED) (UNII: K6MOM3T5YL)	

FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)

MAGNESIUM STEARATE (UNII: 70097M6I30)

MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)

Product Characteristic	uct Characteristics			
Color	BLUE	Score	no score	
Shape	OVAL	Size	16mm	
Flavor		Imprint Code	L2X2	
Contains				

F	Packaging				
#	tem Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:81522-006- 60	1 in 1 CARTON	11/02/2021		
1		20 in 1 BOTTLE; Type 0: Not a Combination Product			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA078912	11/02/2021		

Labeler - FSA Store Inc. (049283340)

Revised: 11/2021 FSA Store Inc.