MUCINEX- guaifenes in tablet, extended release Rebel Distributors Corp

Mucinex[®]

Drug Facts

Active ingredient (in each extended-release bi-layer 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.

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 934P, NF; FD&C blue #1 aluminum lake; hypromellose, USP; magnesium stearate, NF; microcrystalline cellulose, NF; sodium starch glycolate, NF

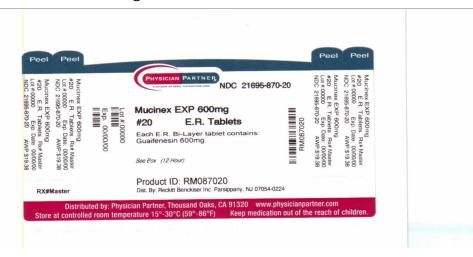
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Repackaged by:

Rebel Distributors Corp

Thousand Oaks, CA 91320

PRINCIPAL DISPLAY PANEL - 600 mg Tablet Carton



MUCINEX

guaifenesin tablet, extended release

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Prod	uct	Intor	mation

Product Type HUMAN OTC DRUG Item Code (Source) NDC:21695-870(NDC:63824-008)

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 934 (UNII: Z135WT9208)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics				
Color	WHITE (blue and white)	Score	no score	
Shape	OVAL	Size	16 mm	
Flavor		Imprint Code	Mucinex;600	
Contains				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:21695-870-20	2 in 1 CARTON			
1		10 in 1 BLISTER PACK			
2	NDC:21695-870-40	4 in 1 CARTON			
2		10 in 1 BLISTER PACK			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021282	03/27/2009	

Labeler - Rebel Distributors Corp (118802834)

Establishment				
Name	Address	ID/FEI	Business Operations	
Rebel Distributors Corp		118802834	RELABEL, REPACK	

Revised: 4/2011 Rebel Distributors Corp