

MUCINEX- guaifenesin tablet, extended release
RB Health (US) LLC

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

- store at 20-25°C (68-77°F)

Inactive ingredients

carbomer homopolymer type B; FD&C blue #1 aluminum lake; hypromellose, USP; magnesium stearate, NF; microcrystalline cellulose, NF; sodium starch glycolate, NF

Questions?

1-866-MUCINEX (1-866-682-4639)

You may also report side effects to this phone number.

Dist. by: RB Health (US)
Parsippany, NJ 07054-0224

Made in England

PRINCIPAL DISPLAY PANEL - 20 Tablet Blister Pack Carton

NDC 63824-008-32

Mucinex®

600 mg guaifenesin
extended-release bi-layer tablets

EXPECTORANT

12

HOUR®

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

20

EXTENDED-RELEASE
BI-LAYER TABLETS



MUCINEX

guaifenesin tablet, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	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 HO MO POL YMER TYPE B (ALL YL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
ALUMINUM O XIDE (UNII: LM26O6933)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63824-008-36	1 in 1 CARTON	07/03/2012	
1		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:63824-008-32	1 in 1 CARTON	07/03/2012	
2		20 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:63824-008-34	2 in 1 CARTON	07/03/2012	
3		20 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:63824-008-69	3 in 1 CARTON	07/03/2012	
4		20 in 1 BLISTER PACK; Type 0: Not a Combination Product		
5	NDC:63824-008-27	4 in 1 CARTON	07/03/2012	
5		18 in 1 BLISTER PACK; Type 0: Not a Combination Product		
6	NDC:63824-008-15	5 in 1 CARTON	07/03/2012	
6		20 in 1 BLISTER PACK; Type 0: Not a Combination Product		
7	NDC:63824-008-74	24 in 1 CARTON	07/03/2012	
7	NDC:63824-008-73	2 in 1 POUCH; Type 0: Not a Combination Product		
8	NDC:63824-008-50	500 in 1 BOTTLE; Type 0: Not a Combination Product	07/03/2012	
9	NDC:63824-008-72	2 in 1 POUCH; Type 0: Not a Combination Product	07/03/2012	
10	NDC:63824-008-86	4 in 1 CARTON	07/03/2012	
10		17 in 1 BLISTER PACK; Type 0: Not a Combination Product		
11	NDC:63824-008-24	2 in 1 CARTON	07/03/2012	
11		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
12	NDC:63824-008-80	4 in 1 CARTON	07/03/2012	
12		20 in 1 BLISTER PACK; Type 0: Not a Combination Product		
13	NDC:63824-008-92	6 in 1 CARTON	07/03/2012	
13		20 in 1 BLISTER PACK; Type 0: Not a Combination Product		
14	NDC:63824-008-17	25 in 1 CARTON	10/01/2018	
14	NDC:63824-008-72	2 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021282	07/03/2012	

Labeler - RB Health (US) LLC (081049410)

Revised: 5/2019

RB Health (US) LLC