MUCINEX- guaifenesin tablet, extended release Bryant Ranch Prepack

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

HOW SUPPLIED

Guaifenesin Extended-Release Bi-Layer Tablets 600 mg

- NDC 63629-7115-1: 30 Tablets in a Bottle
- NDC 63629-7115-2: 20 Tablets in a Bottle
- NDC 63629-7115-3: 60 Tablets in a Bottle
- NDC 63629-7115-4: 40 Tablets in a Bottle
- NDC 63629-7115-5: 14 Tablets in a Bottle

Repackaged/Relabeled by: Bryant Ranch Prepack, Inc. Burbank, CA 91504

Guaifenesin Extended-Release Bi-Layer Tablets 600 mg



MUCINEX

guaifenesin tablet, extended release

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63629-7115(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 HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
ALUMINUM OXIDE (UNII: LMI26O6933)				
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:63629- 7115-1	30 in 1 BOTTLE; Type 0: Not a Combination Product	04/02/2024	
2	NDC:63629- 7115-2	20 in 1 BOTTLE; Type 0: Not a Combination Product	10/17/2016	
3	NDC:63629- 7115-3	60 in 1 BOTTLE; Type 0: Not a Combination Product	04/02/2024	
4	NDC:63629- 7115-4	40 in 1 BOTTLE; Type 0: Not a Combination Product	02/04/2019	
5	NDC:63629- 7115-5	14 in 1 BOTTLE; Type 0: Not a Combination Product	04/02/2024	

Marketing In	formation		
Marketing	Application Number or Monograph	Marketing Start	Marketing End

Category	Citation	Date	Date
NDA	NDA021282	07/03/2012	

Labeler - Bryant Ranch Prepack (171714327)

Registrant - Bryant Ranch Prepack (171714327)

Establishment			
Name	Address	ID/FEI	Business Operations
Bryant Ranch Prepack		171714327	REPACK(63629-7115), RELABEL(63629-7115)

Revised: 4/2024 Bryant Ranch Prepack