

MUCINEX - guaifenesin tablet, extended release
Physicians Total Care, Inc.

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

Distributed by:
Reckitt Benckiser Inc.
Parsippany, NJ 07054-0224
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Relabeling of "Additional Barcode" by:
Physicians Total Care, Inc.
Tulsa, OK 74146

PRINCIPAL DISPLAY PANEL - 600 mg Tablet Carton

NDC 54868-4750-0 20 Tablets

NDC 54868-4750-1 40 Tablets

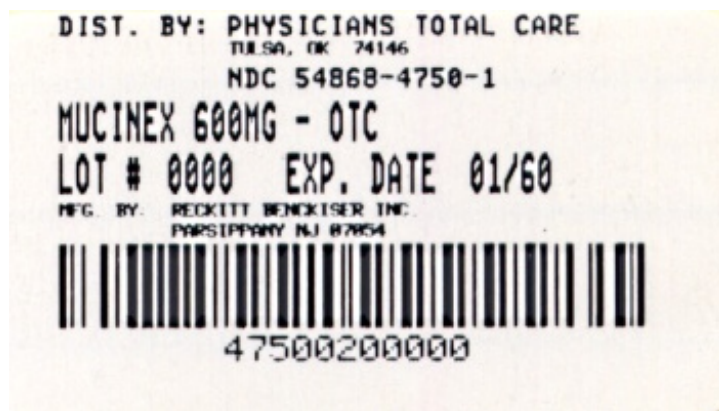
Mucinex®
600 mg guaifenesin extended-release bi-layer tablets

EXPECTORANT

12
HOUR

NEW LOOK –
SAME RELIEF

Thins And Loosens Mucus Relieves Chest Congestion



MUCINEX

guaifenesin tablet, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54868-4750(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)	
HYPROMELLOSE (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (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:54868-4750-1	2 in 1 CARTON		
1		10 in 1 BLISTER PACK		
2	NDC:54868-4750-0	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	03/05/2003	

Labeler - Physicians Total Care, Inc. (194123980)

Establishment			
Name	Address	ID/FEI	Business Operations
Physicians Total Care, Inc.		194123980	relabel