GUAIFENESIN EXTENDED RELEASE- guaifenesin tablet, extended release PUBLIX SUPER MARKETS, INC

GUAIFENESIN EXTENDED-RELEASE TABLETS

Drug Facts

Active ingredient (in each extended-release tablet)

Guaifenesin, USP 1200 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 extended-release 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 extended-release tablet every 12

hours. Do not exceed 2 extended-release tablets in 24 hours.

• children under 12 years of age: do not use

Other information

- store between 68-77°F (20-25°C)
- TAMPER EVIDENT: DO NOT USE IF CARTON IS OPEN OR IF PRINTED SEAL ON BLISTER IS BROKEN OR MISSING.

Inactive ingredients

colloidal silicon dioxide, FD&C blue #2 aluminum lake, hypromellose, magnesium stearate, povidone.

DISTRIBUTED BY PUBLIX SUPER MARKETS, INC., 3300 PUBLIX CORPORATE PARKWAY LAKELAND, FL 33811

PRINCIPAL DISPLAY PANEL - 1200 mg Extended-Release Tablet Blister Pack Carton

NDC 41415-997-14

12-HOUR MAXIMUM STRENGTH mucusrelief GUAIFENESIN EXTENDED-RELEASE TABLETS, 1200 mg EXPECTORANT

12 Hour

- Relieves Chest Congestion
- Thins and Loosens Mucus

14 EXTENDED-RELEASE TABLETS

[†]Compare to the active ingredient of Mucinex[®] Maximum Strength





mucusreliet

GUAIFENESIN EXTENDED-RELEASE TABLETS, 1200 mg 12-HOUR MAXIMUM STRENGTH

EXTENDED-RELEASE TABLETS



NDC 41415-997-14

12-HOUR MAXIMUM STRENGTH

mucusrelief

GUAIFENESIN EXTENDED-RELEASE TABLETS, 1200 mg

EXPECTORANT



ACTUAL SIZE

12 Hour

- · Relieves Chest Congestion
- Thins and Loosens Mucus

EXTENDED-RELEASE TABLETS

Lot No.

†Compare to the active ingredient of Mucinex®

Maximum Strength

Expiration Date:



EXPECTORANT

GUAIFENESIN EXTENDED-RELEASE TABLETS, 1200 mg **mucus**reliei 2-HOUR MAXIMUM STRENGTH

- TABLETS



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Drug Facts (continued)

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Inactive ingredients

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Keep the carton. It contains important information. See end panel for expiration date.

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guaifenesin tablet, extended release

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:41415-997

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength
	Consideration (UNIV. ACENTALIANO) (Consideration UNIV. ACENTALIANO)	Cualfamaala	1200

Guaifenesin (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ) Guaifenesin 1200 mg

Inactive Ingredients

•			
Ingredient Name	Strength		
hypromellose, unspecified (UNII: 3NXW29V3WO)			
magnesium stearate (UNII: 70097M6I30)			
silicon dioxide (UNII: ETJ7Z6XBU4)			
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)			
POVIDONE, UNSPECIFIED (UNII: FZ 989GH94F)			

Product Characteristics

1 Todace Characteristics				
Color	WHITE	Score	no score	
Shape	OVAL	Size	22mm	
Flavor		Imprint Code	RH99	
Contains				

Packaging

П		9 9				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
	1	NDC:41415- 997-14	1 in 1 CARTON	12/10/2017		
	1		14 in 1 BLISTER PACK; Type 0: Not a Combination Product			

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
ANDA	ANDA209254	12/10/2017	

Labeler - PUBLIX SUPER MARKETS, INC (006922009)

Establishment

LStabilishinent					
Name	Address	ID/FEI	Business Operations		

Ohm Laboratories Inc. 184769029 MANUFACTURE(41415-997)

Revised: 2/2022 PUBLIX SUPER MARKETS, INC