

**GUAIFENESIN EXTENDED RELEASE- guaifenesin tablet, extended release**  
**CHAIN DRUG MARKETING ASSOCIATION INC**

-----  
**Guaifenesin Extended-Release Tablets 1200 mg**

***Drug Facts***

**Active ingredient (in each extended-release tablet)**

Guaifenesin 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 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 tablet every 12 hours. Do not exceed 2 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 homopolymer type B; hypromellose, USP; magnesium stearate, NF; microcrystalline cellulose, NF; sodium starch glycolate, NF

## Questions?

**(1-800-406-7984)**

You may also report side effects to this phone number.

Distributed by C.D.M.A., Inc.©  
43157 W. Nine Mile  
Novi, MI 48375

## PRINCIPAL DISPLAY PANEL - 1200 mg Tablet Blister Pack Carton

**NDC 63868-390-14**

**QC®  
QUALITY  
CHOICE**

**† Compare to  
Active Ingredient in  
Maximum Strength  
Mucinex®**

**Maximum Strength**

**Mucus Relief**

**Guaifenesin  
Extended-Release  
Tablets 1200 mg**

**Expectorant**

**12 Hour**

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

**14 Extended-Release Tablets**



Maximum Strength  
**Mucus Relief**  
 Guaifenesin Extended-Release Tablets 1200 mg  
 Expectorant

NDC 63868-390-14



Compare to  
 Active Ingredient in  
 Maximum Strength  
 Mucinex®

Maximum Strength

# Mucus Relief

Guaifenesin  
 Extended-Release  
 Tablets 1200 mg

Expectorant

12 Hour

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



14 Extended-Release Tablets

Lot No.

Expiration Date:

**NON VARNISH**



Maximum Strength  
**Mucus Relief**  
 Guaifenesin Extended-Release Tablets 1200 mg  
 Expectorant



Maximum Strength  
**Mucus Relief**  
 Guaifenesin Extended-Release Tablets 1200 mg  
 Expectorant



5142027

**Drug Facts**

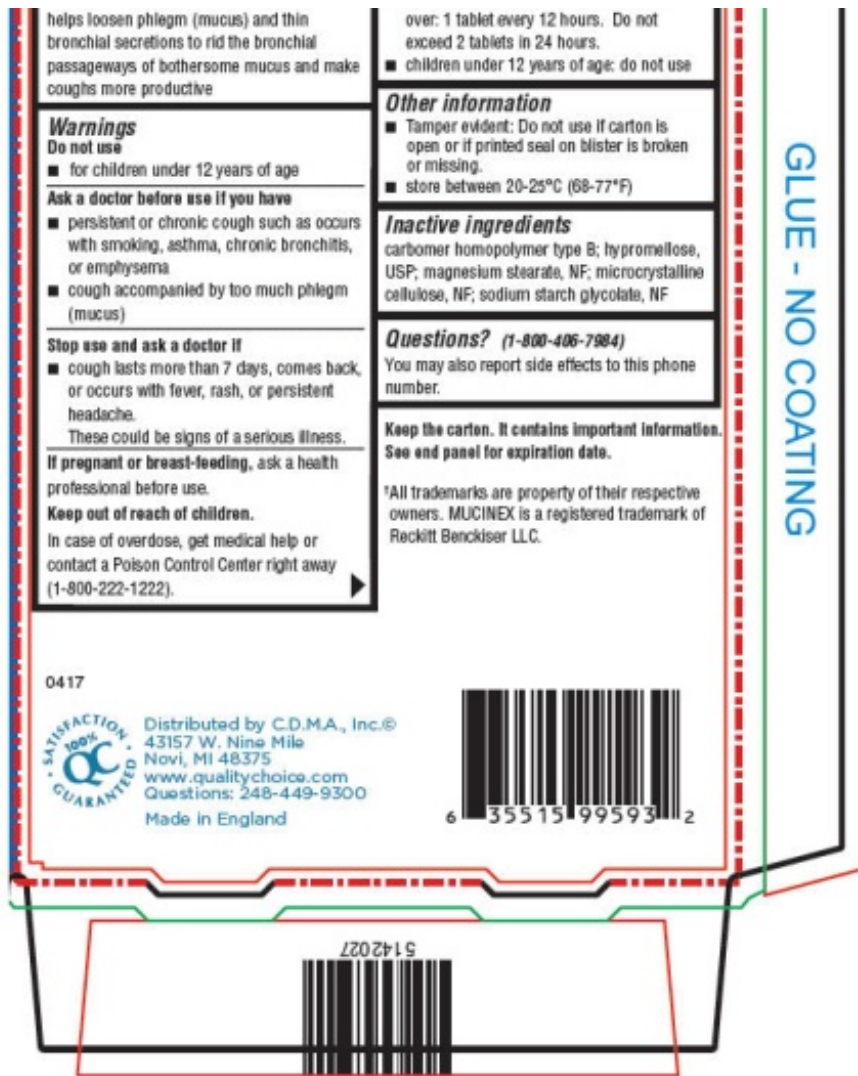
Active ingredient (in each extended-release tablet)	Purpose
Guaifenesin 1200 mg.....	Expectorant

**Uses**

**Drug Facts (continued)**

**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



## GUAIFENESIN EXTENDED RELEASE

guaifenesin tablet, extended release

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63868-390
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Guaifenesin (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)	Guaifenesin	1200 mg

### Inactive Ingredients

Ingredient Name	Strength
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)	
hypromellose, unspecified (UNII: 3NXW29V3WO)	
magnesium stearate (UNII: 70097M61B0)	

microcrystalline cellulose (UNII: OP1R32D61U)

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

### Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	22mm
<b>Flavor</b>		<b>Imprint Code</b>	Mxeunic;1200
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-390-14	1 in 1 CARTON	12/10/2017	
1		14 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:63868-390-28	2 in 1 CARTON	12/10/2017	
2		14 in 1 BLISTER PACK; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021282	10/15/2017	

**Labeler** - CHAIN DRUG MARKETING ASSOCIATION INC (011920774)

### Establishment

Name	Address	ID/FEI	Business Operations
RECKITT BENCKISER HEALTHCARE INTERNATIONAL LTD		230780363	MANUFACTURE(63868-390)

Revised: 10/2018

CHAIN DRUG MARKETING ASSOCIATION INC