

**GUAIFENESIN EXTENDED RELEASE 600 MG- guaifenesin tablet  
GUAIFENESIN EXTENDED RELEASE 1200 MG- guaifenesin tablet  
TIME CAP LABORATORIES, INC.**

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**Guaifenesin Extended-Release Tablets 600 mg and 1200 mg**

**OTC - ACTIVE INGREDIENT SECTION**

**For 600 mg:**

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

Guaifenesin, USP 600 mg

**For 1200 mg:**

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

Guaifenesin, USP 1200 mg

**OTC - PURPOSE SECTION**

***Purpose***

Expectorant

**INDICATIONS & USAGE SECTION**

***Uses***

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive

**WARNINGS SECTION**

**OTC - DO NOT USE SECTION**

**Do not use**

- for children under 12 years of age

**OTC - ASK DOCTOR SECTION**

**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)

## **OTC - STOP USE SECTION**

### **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.

## **OTC - PREGNANCY OR BREAST FEEDING SECTION**

**If pregnant or breast-feeding**, ask a health professional before use.

## **OTC - KEEP OUT OF REACH OF CHILDREN SECTION**

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

## **DOSAGE & ADMINISTRATION SECTION**

### ***Directions***

#### **For 600 mg**

- 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 or 2 extended - release tablets every 12 hours. Do not exceed 4 extended - release tablets in 24 hours.
- children under 12 years of age: do not use

#### **For 1200 mg**

- 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

## **STORAGE AND HANDLING SECTION**

### ***Other information***

- store at 20-25°C (68-77°F)

## **INACTIVE INGREDIENT SECTION**

***Inactive ingredients*** colloidal silicon dioxide, copovidone, FD&C blue No. 1 aluminum lake, hypromellose, magnesium stearate, maltodextrin, microcrystalline cellulose, povidone (K-30), sodium starch glycolate, stearic acid


# OTC - QUESTIONS SECTION

Questions or comments? Call 1-877-290-4008

## PRINCIPAL DISPLAY PANEL

Adhesive Area

<p><b>Drug Facts (continued)</b>                  medical help or contact a Poison Control Center (1-800-222-1222) right away.</p>	<p><b>Directions</b>                  ■ 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</p>
<p><b>Other Information</b>                  ■ store at 20-25°C (68-77°F)</p>	<p><b>Inactive ingredients</b> colloidal silicon dioxide, copovidone, FD&amp;C blue no. 1 aluminum lake, hypromellose, magnesium stearate, maltodextrin, microcrystalline cellulose, povidone (K-30), sodium starch glycolate, stearic acid.</p>
<p><b>Questions or comments?</b> Call 1-877-290-4008</p>	



NDC 49483-724-70

<sup>†</sup>Compare to the active ingredient in Maximum Strength Mucinex®

TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF THE IMPRINTED FOIL SEAL OVER THE MOUTH OF THE BOTTLE IS CUT, TORN, BROKEN OR MISSING

MAXIMUM STRENGTH


## Guafenesin Extended-Release Tablets 1200 mg

Expectorant  
12 HOUR

- Relieves chest congestion
- Thins and loosens mucus
- Immediate and Extended Release


70

EXTENDED-RELEASE TABLETS



<p><b>Drug Facts</b></p> <p><b>Active ingredient (in each extended-release tablet)</b>                  Guaifenesin, USP 1200 mg.....Expectorant</p>	<p><b>Purpose</b>                  ■ helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive</p>
<p><b>Uses</b>                  ■ helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive</p>	<p><b>Warnings</b>                  ■ Do not use                  ■ for children under 12 years of age</p>
<p><b>Ask a doctor before use if you have</b>                  ■ persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema                  ■ cough accompanied by too much phlegm (mucus)</p>	<p><b>Stop use and ask a doctor if</b>                  ■ cough lasts more than 7 days, comes back, or occurs with fever, rash, or persistent headache. These could be signs of a serious illness.</p>
<p><b>If pregnant or breast-feeding, ask a health professional before use.</b>  <b>Keep out of reach of children.</b> In case of overdose, get</p>	<p><b>Drug Facts (continued under label)</b></p> <p><small>*This product is not manufactured or distributed by RB Health US LLC, owner of the registered trademark Maximum Strength Mucinex®.</small></p> <p>Distributed by:                  Time-Cap Labs, Inc.                  7 Michael Avenue,                  Farmingdale, NY 11735                  724R 0124 Made in India</p>

40186701 Code No.: 600DRUGS/515



3 7 0 7 2 4 8 3 4 4 1 1 7 2 2 4 7 0

Varnish Omit Area

LOT:   
SEE HERE   
 EXP:..

NDC 49483-723-50

**timely™**

\*Compare to the active ingredient in Mucinex®

# Guaifenesin Extended-Release Tablets **600 mg**

Expectorant  
**12 HOUR**

- Relieves chest congestion
- Thins and loosens mucus
- Immediate and Extended Release



Actual Size

**500** EXTENDED-RELEASE TABLETS

**Drug Facts**

**Active ingredient (in each extended-release tablet)**  
Guaifenesin, USP 600 mg.....Expectorant

**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 (1-800-222-1222) right away.

**Drug Facts (continued)**

**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 or 2 extended-release tablets every 12 hours. Do not exceed 4 extended-release 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**  
colloidal silicon dioxide, copovidone, FD&C blue no. 1 aluminum lake, hypromellose, magnesium stearate, maltodextrin, microcrystalline cellulose, povidone (K-30), sodium starch glycolate, stearic acid.

**Questions or comments?**  
Call 1-877-290-4008

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Time-Cap Labs, Inc.  
7 Michael Avenue,  
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723R 0124  
Made in India

**TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF THE IMPRINTED FOIL SEAL OVER THE MOUTH OF THE BOTTLE IS CUT, TORN, BROKEN OR MISSING**



#118891 Code No.: 00PRUS515

LOT:  
EXP.:

Varnish Omit Area

GUAIFENESIN EXTENDED RELEASE 600 MG			
guaifenesin tablet			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49483-723
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		
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
COPOVIDONE K25-31 (UNII: D9C330MD8B)			
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)			
MAGNESIUM STEARATE (UNII: 70097M6130)			
MALTODEXTRIN (UNII: 7CVR7L4A2D)			
MICROCRYSTALLINE CELLULOSE 102 (UNII: PNR0YF693Y)			
POVIDONE K30 (UNII: U725QWY32X)			
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)			
STEARIC ACID (UNII: 4ELV7Z65AP)			
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)			
Product Characteristics			
Color	white (Blue and White)	Score	no score
Shape	OVAL	Size	16mm
Flavor		Imprint Code	42
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49483-723-50	500 in 1 BOTTLE; Type 0: Not a Combination Product	01/08/2024	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA217780	01/08/2024	

## GUAIFENESIN EXTENDED RELEASE 1200 MG

guaifenesin tablet

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49483-724
Route of Administration	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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE 102 (UNII: PNR0YF693Y)	
POVIDONE K30 (UNII: U725QWY32X)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)	
COPOVIDONE K25-31 (UNII: D9C330MD8B)	

### Product Characteristics

Color	white (Blue and White)	Score	no score
Shape	CAPSULE	Size	22mm
Flavor		Imprint Code	41
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49483-724-70	70 in 1 BOTTLE; Type 0: Not a Combination Product	01/08/2024	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA217780	01/08/2024	

**Labeler** - TIME CAP LABORATORIES, INC. (037052099)

**Registrant** - TIME CAP LABORATORIES, INC. (037052099)

## Establishment

Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LIMITED		925822975	manufacture(49483-724, 49483-723)

Revised: 2/2024

TIME CAP LABORATORIES, INC.