

**GUAIFENESIN- guaifenesin tablet**  
**SAM'S WEST INC**

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**Maximum Strength**  
**Mucus Relief**

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

**Expectorant**

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

**Active Ingredient (in each extended-release bi-layer 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 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, magnesium stearate, microcrystalline cellulose, sodium starch glycolate

### **Questions?**

We would love to hear about your Member's Mark experience! Call us toll-free at **1-877-770-3183** Mon-Fri 8:00 AM EST to 5:00 PM PST

### **PDP**



# GUAIFENESIN

guaifenesin tablet

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68196-405
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	1200 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>CARBOMER HOMOPOLYMER TYPE B (ALLYL SUCROSE CROSSLINKED)</b> (UNII: Z135WT9208)	

**SODIUM STARCH GLYCOLATE TYPE A** (UNII: H8AV0SQX4D)

**HYPROMELLOSE 2910 (5 MPA.S)** (UNII: R75537T0T4)

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	OVAL ((Elliptical))	<b>Size</b>	22mm
<b>Flavor</b>		<b>Imprint Code</b>	G;1200
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68196-405-14	56 in 1 BLISTER PACK; Type 0: Not a Combination Product	10/06/2023	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA213420	10/06/2023	

**Labeler** - SAM'S WEST INC (051957769)

Revised: 2/2024

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