

**GUAIFENESIN EXTENDED RELEASE- guaifenesin tablet, extended release
SAM'S WEST INC**

**Guaifenesin
Extended Release**

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 20-25°C (68-77°F)
- **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.

Questions?

call toll-free Monday to Friday 8:30 am to 5:00 pm EST at **1-800-406-7984**.

DISTRIBUTED BY:
SAM'S WEST, INC.
BENTONVILLE, AR 72716

PRINCIPAL DISPLAY PANEL - 1200 mg Tablet Blister Pack Carton

Compare to Maximum Strength Mucinex[®]
active ingredient*

NDC 68196-996-56

Member's Mark[™]

Maximum Strength

Mucus Relief

Guaifenesin Extended-Release
Tablets, 1200 mg
Expectorant

- Relieves chest congestion
- Thins and loosens mucus

12
HOUR

56
Extended-

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68196-996
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
hypromellose, unspecified (UNII: 3NXW29V3WO)	
magnesium stearate (UNII: 70097M6I30)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
povidone, unspecified (UNII: FZ989GH94E)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	

Product Characteristics

Color	WHITE	Score	no score
Shape	OVAL	Size	22mm
Flavor		Imprint Code	RH;99
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68196-996-56	4 in 1 CARTON	01/12/2022	
1		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
ANDA	ANDA209254	01/12/2022	

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

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		184769029	MANUFACTURE(68196-996)

