

GUAIFENESIN - guaifenesin tablet, extended release
Sam's West Inc

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 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° to 25°C (68° to 77°F)

Inactive ingredients

colloidal silicon dioxide, hypromellose, magnesium stearate, microcrystalline cellulose, povidone, and pregelatinised starch (maize)

Questions?

1-855-274-4122 (Monday – Friday 8:30 AM to 5:00 PM EST)

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

Made in India

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 1200 mg Blister Carton (56 (4 x 14) Tablets)

**Member's
Mark™**

COMPARE TO **MAXIMUM STRENGTH
MUCINEX® ACTIVE INGREDIENT***

NDC 68196-960-56

MAXIMUM STRENGTH

Mucus Relief

GUAIFENESIN EXTENDED-RELEASE TABLETS, 1200 mg

GUAIFENESIN 1200 mg-EXPECTORANT

Relieves chest congestion

Actual Size

56

Extended-Release

Tablets

- **Relieves chest congestion**
- **Thins and loosens mucus**

12

HR



guaifenesin tablet, extended release				
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68196-960	
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 2208 (15000 MPA.S) (UNII: Z78RG6M2N2)				
HYPROMELLOSE 2910 (10000 MPA.S) (UNII: 0HO1H52958)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
MICROCRYSTALLINE CELLULOSE 101 (UNII: 7T9FYH5QMK)				
MICROCRYSTALLINE CELLULOSE 102 (UNII: PNR0YF693Y)				
POVIDONE K90 (UNII: RDH86HJV5Z)				
POVIDONE K25 (UNII: K0KQV10C35)				
STARCH, CORN (UNII: O8232NY3SJ)				
Product Characteristics				
Color	WHITE (white to off-white)	Score	no score	
Shape	OVAL	Size	21mm	
Flavor		Imprint Code	L;69	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68196-960-56	4 in 1 CARTON	07/31/2025	
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		ANDA210453	07/31/2025	

Labeler - Sam's West Inc (051957769)

Registrant - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650918514	ANALYSIS(68196-960) , MANUFACTURE(68196-960)

Revised: 8/2025

Sam's West Inc