

MUCUS RELIEF- guaifenesin tablet
Sam's West Inc

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Simply Right 44-532-Delisted

Active ingredient (in each immediate-release tablet)

Guaifenesin 400 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

Ask a doctor before use if you have

- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema

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 condition.

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.

Directions

- take with a full glass of water
- **adults and children 12 years of age and over:** 1 tablet, every 4 hours. Do not take more than 6 tablets in 24 hours.
- **children under 12 years:** do not use

Other information

- store at controlled room temperature 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

Inactive ingredients

FD&C blue #1 aluminum lake, hypromellose, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, povidone, silicon dioxide, sodium starch glycolate, stearic acid

Questions?

To Report Adverse Drug Event Call: (800) 616-2471

Principal Display Panel

NDC 68196-532-06 **chest congestion**

SIMPLY RIGHT™

Health Care

mucus relief

guaifenesin | expectorant

relieves chest congestion, thins and loosens mucus

1 tablet dose

immediate release

200 tablets

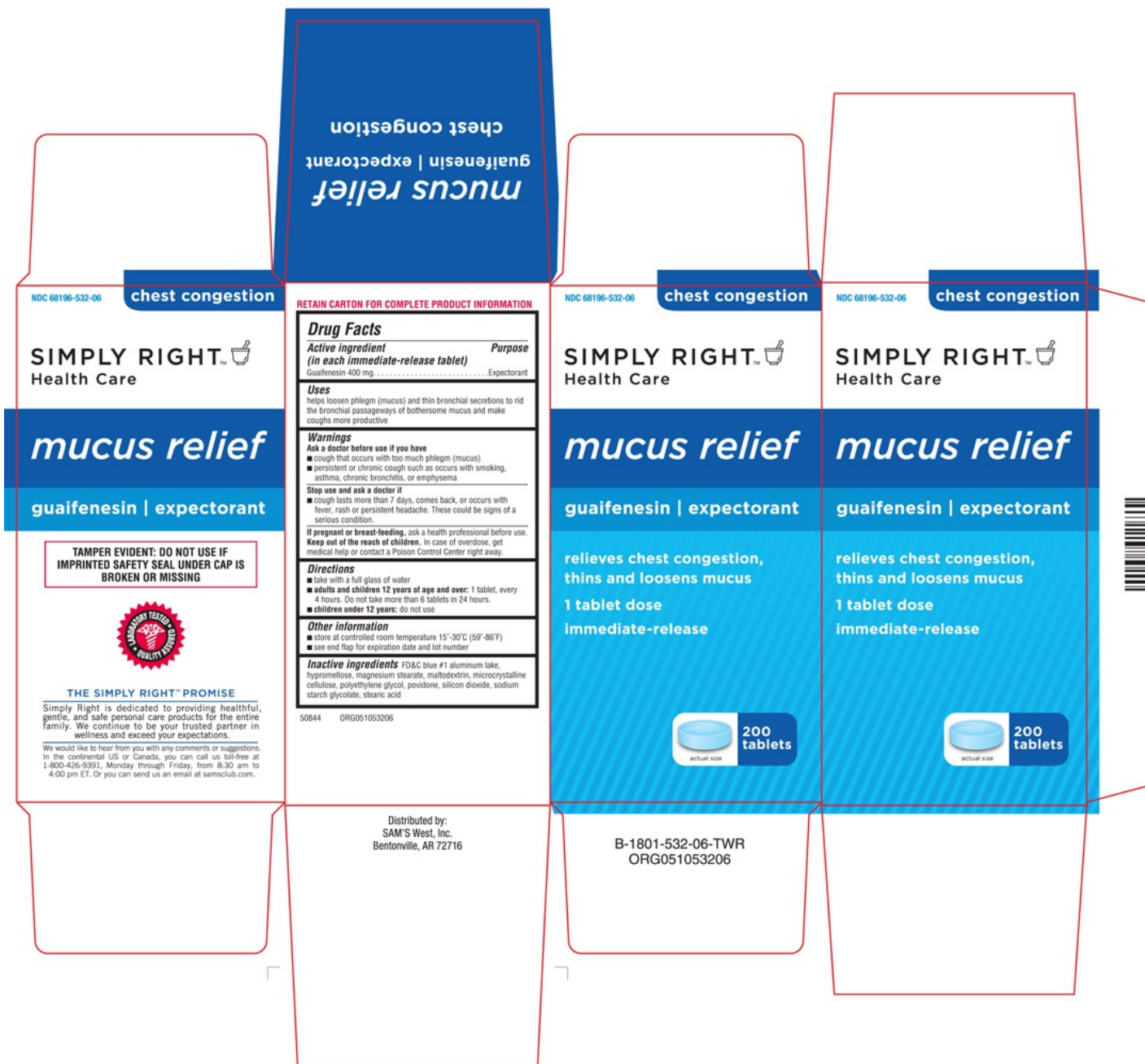
**TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS
BROKEN OR MISSING**

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Distributed by:

SAM'S West, Inc.

Bentonville, AR 72716



Simply Right 44-532

MUCUS RELIEF

guaifenesin tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68196-532
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics

Color	BLUE	Score	2 pieces
Shape	ROUND	Size	13mm
Flavor		Imprint Code	44;532
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68196-532-06	1 in 1 CARTON	12/22/2005	08/03/2018
1		200 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	12/22/2005	08/03/2018

Labeler - Sam's West Inc (051957769)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(68196-532)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(68196-532)