

GUAIFENESIN AND DEXTROMETHORPHAN HYDROBROMIDE- guaifenesin and dextromethorphan hydrobromide tablet, extended release
SAM'S WEST INC

Guaifenesin and Dextromethorphan HBr

Drug Facts

<i>Active ingredients (in each extended-release tablet)</i>	<i>Purposes</i>
Dextromethorphan HBr 60 mg	Cough suppressant
Guaifenesin 1200 mg	Expectorant

Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
- temporarily relieves:
 - cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants
 - the intensity of coughing
 - the impulse to cough to help you get to sleep

Warnings

Do not use

- for children under 12 years of age
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

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)

When using this product

- do not use more than directed

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 and older: 1 extended-release tablet every 12 hours; not more than 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)

Inactive ingredients

carbomer homopolymer, colloidal silicon dioxide, hypromellose, magnesium stearate, maltodextrin, microcrystalline cellulose, povidone (K-30), stearic acid

Questions?

(1-800-406-7984)

You may also report side effects to this phone number.

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

PRINCIPAL DISPLAY PANEL - 56 Extended-Release Tablet Blister Pack Carton

Compare to Maximum Strength Mucinex[®] DM
active ingredients*

NDC 68196-997-56

Member's Mark[™]

Maximum Strength
Mucus Relief DM

Guaifenesin 1200 mg &
Dextromethorphan HBr 60 mg
Extended-Release Tablets
Expectorant & Cough Suppressant

- Controls cough
- Thins and loosens mucus
- Immediate and Extended Release

12
HOUR

56
Extended-
Release
Tablets

* All trademarks are property of their respective owners. This product is not affiliated with the makers/owners of Mucinex® DM.

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(in each extended-release tablet)
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Guaifenesin 1200 mg

Purposes
Cough suppressant
Expectorant



Maximum Strength

Mucus Relief DM

**Guaifenesin 1200 mg &
Dextromethorphan HBr 60 mg
Extended-Release Tablets
Expectorant & Cough Suppressant**

- Controls cough
- Thins and loosens mucus
- Immediate and Extended Release

**Compare to Maximum Strength Mucinex® DM
active ingredients***

NDC 68196-997-56

M Member's Mark™



actual size

56
Extended-
Release
Tablets

Maximum Strength

Mucus Relief DM

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Expectorant & Cough Suppressant

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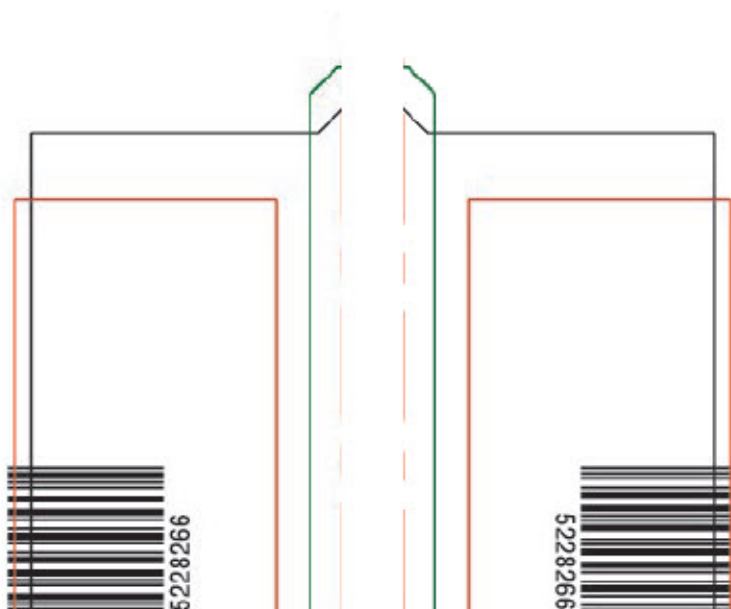
M Member's Mark™

Maximum Strength

Mucus Relief DM

Guaifenesin 1200 mg &
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Extended-Release Tablets
Expectorant & Cough Suppressant

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NON VARNISH

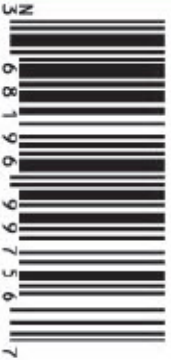
Expiration Date:

Lot No.

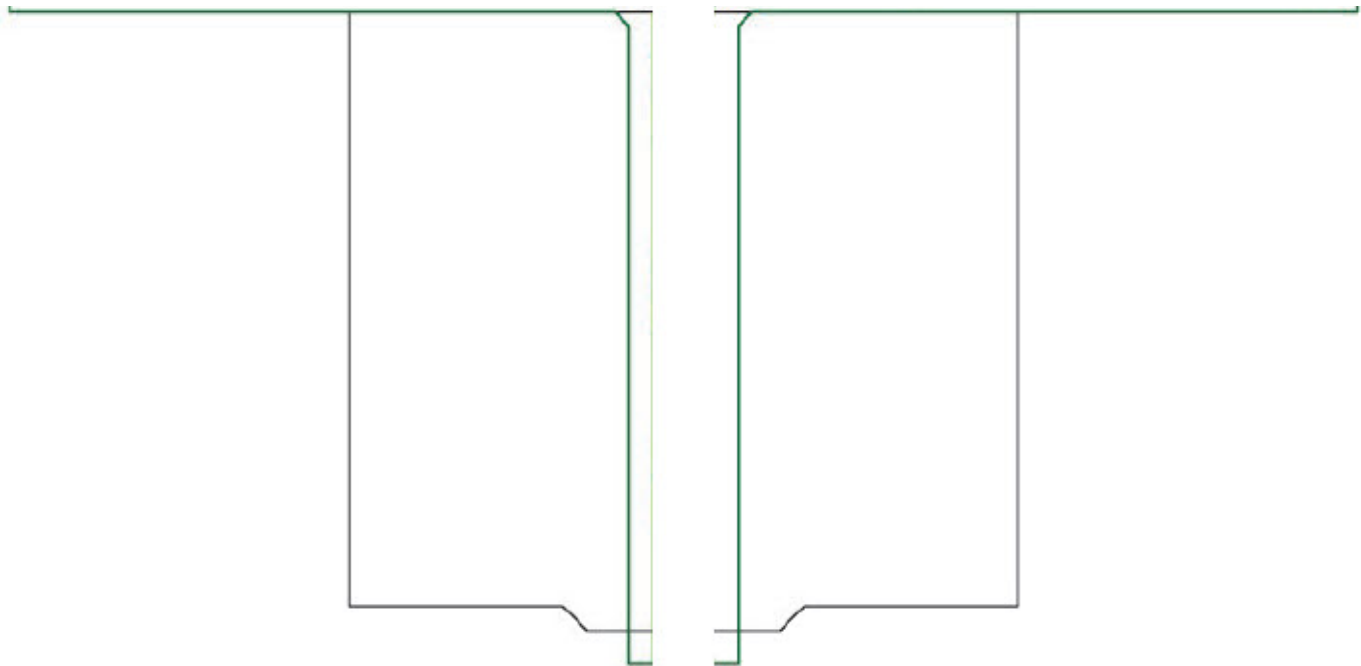
**Keep the carton. It contains important information.
See end panel for expiration date.**

For product questions, call:
1-800-406-7984 (toll-free),
8am - 5pm CST Monday - Friday.

PARENTS:
Learn about teen medicine abuse
www.StopMedicineAbuse.org



DISTRIBUTED BY:
SAM'S WEST, INC.
BENTONVILLE, AR 72716
MADE IN INDIA
0122



GUAIFENESIN AND DEXTROMETHORPHAN HYDROBROMIDE

guaifenesin and dextromethorphan hydrobromide tablet, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68196-997
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Guaifenesin (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)	Guaifenesin	1200 mg
Dextromethorphan Hydrobromide (UNII: 9D2RTI9KYH) (Dextromethorphan - UNII:7355X3ROTS)	Dextromethorphan Hydrobromide	60 mg

Inactive Ingredients

Ingredient Name	Strength
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01Z NK31)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
POVIDONE K30 (UNII: U725QWY32X)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	WHITE (off-white)	Score	no score
Shape	OVAL	Size	16mm
Flavor		Imprint Code	053
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68196-997-56	1 in 1 CARTON	02/16/2022	
1		4 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	ANDA214781	02/16/2022	

Labeler - SAM'S WEST INC (051957769)

Registrant - SUN PHARMACEUTICAL INDUSTRIES, INC. (146974886)

Establishment

Name	Address	ID/FEI	Business Operations
Sun Pharmaceutical Industries Limited		650456002	MANUFACTURE(68196-997)

Revised: 2/2022

SAM'S WEST INC