

MUCUS RELIEF DM - guaifenesin and dextromethorphan hbr tablet, extended release

Ahold U.S.A., Inc,

Drug Facts

Active ingredients

(in each extended-release tablet)

Dextromethorphan Hydrobromide USP 60 mg

Guaifenesin USP 1200 mg

Purpose

Cough suppressant

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 (1-800-222-1222) right away.

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 and older: 1 tablet every 12 hours; not more than 2 tablets in 24 hours
- children under 12 years of age: do not use

Other information

- tamper evident: do not use if seal over bottle opening is broken or missing
- store at 20° to 25°C (68° to 77°F)

Inactive ingredients

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

Questions?

call **1-877-846-9949** You may also report side effects to this phone number.

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 1200 mg/60 mg (14 Tablet Bottle)

NDC 60000-057-65

CAREone®

MUCUS RELIEF DM

Guaifenesin 1200 mg / Dextromethorphan HBr 60 mg

Extended-Release Tablets

Expectorant/Cough Suppressant

Maximum Strength

Controls Cough

Thins and Loosens Mucus

14 EXTENDED-RELEASE TABLETS

Top Layer Printing side

	NDC 60000-057-65	DISTRIBUTED BY: FOODHOLD, U.S.A., LLC LANDOVER, MD 20785 1-877-846-9949 © 2017 S&S Brands, LLC	Lift Here for <i>Drug Facts</i>
MUCUS RELIEF DM		Quality guaranteed or your money back. www.Care1.info	
Guaifenesin 1200 mg / Dextromethorphan HBr 60 mg Extended-Release Tablets Expectorant/Cough Suppressant		Made in India	
Maximum Strength Controls Cough Thins and Loosens Mucus		M.L.No.: 22/MN/AP/2009/FR	LM - 2528
14 EXTENDED-RELEASE TABLETS		Lot: Exp:	

Top Layer Adhesive side

LM-2528	Drug Facts	
	Active ingredients (in each extended-release tablet)	Purpose
	Dextromethorphan Hydrobromide USP 60 mg.....	Cough suppressant
	Guaifenesin USP 1200 mg.....	Expectorant
	Uses	
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	■ the intensity of coughing	
	■ the impulse to cough to help you get to sleep	
		

Gluing Area

2nd Layer Printing side

2nd Layer Timing side

Gluing Area

Drugs Facts (Continued)

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 (1-800-222-1222) right away. →

Lift Here

LM-2528

2nd Layer Adhesive side

Drugs Facts (Continued)

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 and older: 1 tablet every 12 hours; not more than 2 tablets in 24 hours ■ children under 12 years of age: do not use

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LM-2528

Gluing Area

Base Layer

Gluing Area



NDC 60000-057-65

MUCUS RELIEF DM

Guafenesin 1200 mg / Dextromethorphan HBr 60 mg
Extended-Release Tablets
Expectorant/Cough Suppressant

Maximum Strength

Controls Cough
Thins and Loosens Mucus

14 EXTENDED-RELEASE TABLETS



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Quality guaranteed or your money back.
www.Care1.info

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

LM-2528

Carton Label)

NDC 60000-057-65

CARE One®

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

MUCUS

RELIEF DM

Guaifenesin 1200 mg /

Dextromethorphan HBr 60 mg

Extended-Release Tablets

Expectorant/Cough Suppressant

Maximum Strength

Controls Cough

Thins and Loosens Mucus

12h

OUR PHARMACISTS

Rx

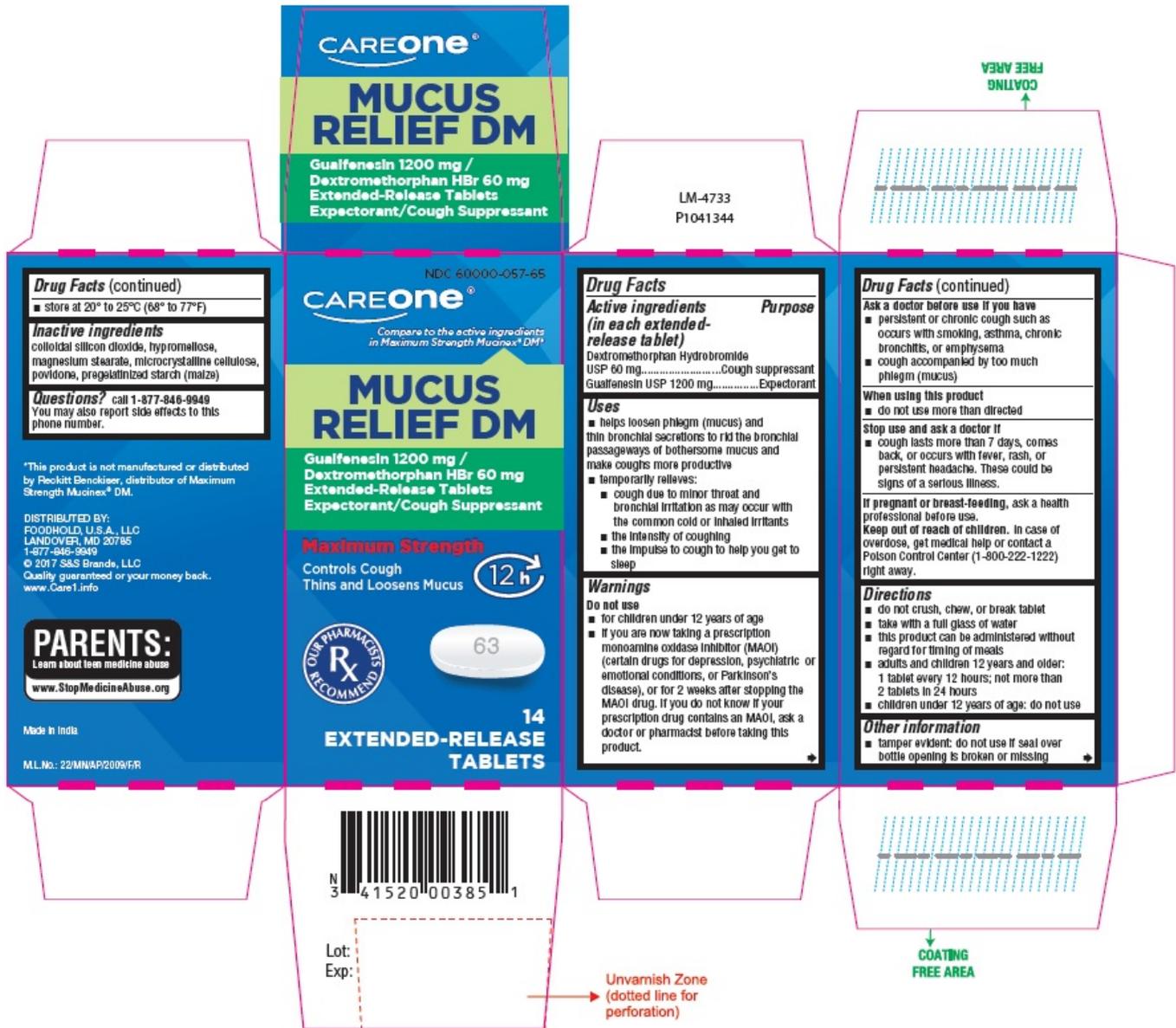
RECOMMENDED

63

14

EXTENDED-RELEASE

TABLETS



MUCUS RELIEF DM

guaifenesin and dextromethorphan hbr tablet, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60000-057
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
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	22mm
Flavor		Imprint Code	X;63
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60000-057-65	1 in 1 CARTON	03/17/2017	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA206941	03/17/2017	

Labeler - Ahold U.S.A., Inc, (188910863)

Registrant - Aurohealth LLC (078728447)

Establishment			
Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(60000-057) , MANUFACTURE(60000-057)

Revised: 12/2023

Ahold U.S.A., Inc,