MUCUS DM - guaifenesin and dextromethorphan hbr tablet, extended release

Amerisource Bergen

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 carton is open or if printed seal on blister 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 1-855-274-4122 You may also report side effects to this phone number.

*This product is not manufactured or distributed by Reckitt Benckiser, distributor of Maximum Strength Mucinex® DM.

Distributed By

AmerisourceBergen 1300 Morris Drive Chesterbrook, PA 19087

Questions or Concerns? www.mygnp.com

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

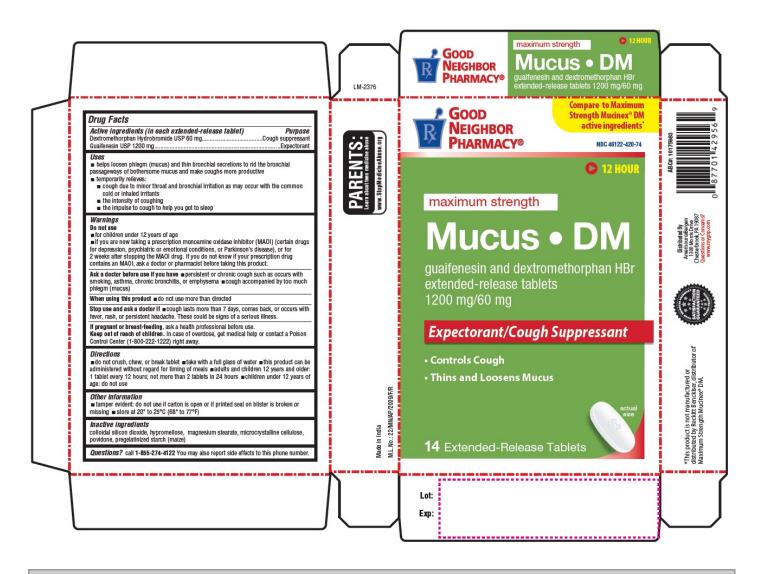
Compare to Maximum Strength Mucinex® DM active ingredients*

GOOD NEIGHBOR PHARMACY®

NDC 46122-420-74
12 Hour
maximum strength
Mucus . DM
guaifenesin and dextromethorphan HBr
extended-release tablets
1200 mg/60 mg
Expectorant/Cough Suppressant

- Controls Cough
- Thins and Loosens Mucus

14 Extended-Release Tablets



MUCUS DM

guaifenesin and dextromethorphan hbr tablet, extended release

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:46122-420
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 Streng		
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:46122-420- 74	2 in 1 CARTON	08/07/2017	
1		7 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:46122-420- 03	4 in 1 CARTON	07/09/2018	
2		7 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	ANDA206941	08/07/2017	

Labeler - Amerisource Bergen (007914906)

Registrant - Aurohealth LLC (078728447)

Establishment			
Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(46122-420), MANUFACTURE(46122-420)

Revised: 3/2024 Amerisource Bergen