GUAIFENESIN AND DEXTROMETHORPHAN HBR - guaifenesin and dextromethorphan hbr tablet, extended release
Aurohealth LLC

Drug Facts

Active Ingredients

(in each extended-release tablet)

Dextromethorphan Hydrobromide USP 30 mg
Guaifenesin USP 600 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 or 2 tablets every 12 hours; not more than 4 tablets in 24 hours
- children under 12 years of age: do not use

Other information

- 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.

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 600 mg/30 mg (14 Tablet Bottle)

NDC 58602-714-05

Mucus Relief DM
Guaifenesin and Dextromethorphan HBr
Extended-release Tablets
600 mg/30 mg
EXPECTORANT AND COUGH SUPPRESSANT
12 HOUR
Controls Cough
Thins and Loosens Mucus
14 Extended-release Tablets
AUROHEALTH

Top Layer Printing side

NDC 58602-714-05

Mucus Relief DM

Guaifenesin and Dextromethorphan HBr Extended-release Tablets 600 mg/30 mg

EXPECTORANT AND COUGH SUPPRESSANT

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

Tamper evident: Do not use if seal over bottle opening is broken or missing

Distributed by:
AUROHEALTH LLC
279 Princeton-Hightstown Road
East Windsor, NJ 08520

Made in India
Code: TS/DRUGS/22/2009

Lift Here for *Drug Facts*

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Lot:
Exp:

Top Layer Adhesive side

P1428462

Drug Facts

Active ingredients (in each extended-release tablet) ***Purpose***

Dextromethorphan Hydrobromide USP 30 mg ..... Cough suppressant

Guaifenesin USP 600 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

Gluing Area

2nd Layer Printing 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

P1428462

2nd Layer Adhesive side

P1428462

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 or 2 tablets every 12 hours; not more than 4 tablets in 24 hours ■children under 12 years of age: do not use

Other information

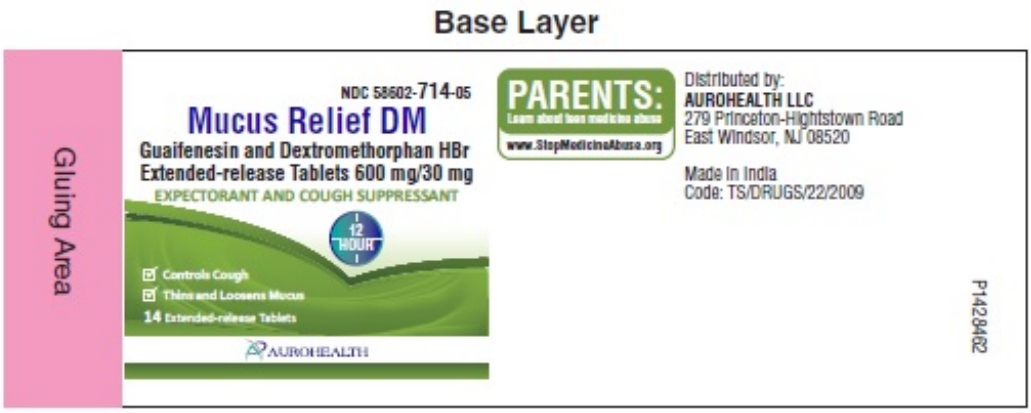
■store at 20° to 25°C (68° to 77°F)

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.

Gluing Area



PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 600 mg/30 mg (14 Tablet Carton Label)

Compare to the active ingredients of Mucinex® DM*
NDC 58602-714-05
Mucus Relief DM
Guaifenesin and Dextromethorphan HBr
Extended-release Tablets
600 mg/30 mg
EXPECTORANT AND COUGH SUPPRESSANT
12 HOUR
Controls Cough
Thins and Loosens Mucus
14 Extended-release Tablets
AUROHEALTH

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 600 mg/30 mg Blister Carton 20 (2 x 10) Unit-dose Tablets

Compare to the active ingredients of Mucinex® DM*
NDC 58602-714-67
Mucus Relief DM
Guaifenesin and Dextromethorphan HBr
Extended-release Tablets
600 mg/30 mg
EXPECTORANT AND COUGH SUPPRESSANT
12 HOUR
Controls Cough
Thins and Loosens Mucus
20 (2 x 10) Extended-release Tablets
AUROHEALTH

GUAIFENESIN AND DEXTROMETHORPHAN HBR

guaifenesin and dextromethorphan hbr tablet, extended release

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58602-714
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	600 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 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**	16mm
Flavor		**Imprint Code**	X;62
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-714-05	1 in 1 CARTON	03/17/2017	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:58602-714-73	1 in 1 CARTON	03/17/2017	
2		20 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:58602-714-09	1 in 1 CARTON	03/17/2017	
3		30 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:58602-714-12	1 in 1 CARTON	03/17/2017	
4		40 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:58602-714-66	1 in 1 CARTON	03/17/2017	
5		58 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:58602-714-15	1 in 1 CARTON	03/17/2017	
6		60 in 1 BOTTLE; Type 0: Not a Combination Product		
7	NDC:58602-714-67	2 in 1 CARTON	03/17/2017	
7	NDC:58602-714-03	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
8	NDC:58602-714-08	4 in 1 CARTON	03/17/2017	
8	NDC:58602-714-03	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
9	NDC:58602-714-07	6 in 1 CARTON	03/17/2017	
9	NDC:58602-714-03	10 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	03/17/2017	

Labeler - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(58602-714) , MANUFACTURE(58602-714)

Revised: 2/2024 Aurohealth LLC