

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

Purposes

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 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 or 2 extended-release tablets every 12 hours; not more than 4 extended-release 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**

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

NDC 58602-714-05

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

Dextromethorphan HBr 30 mg - Cough Suppressant
Guaifenesin 600 mg - Expectorant

RELIEVES COUGH & CHEST CONGESTION

12
HOUR

- ✓ Controls Cough
- ✓ Thins & Loosens Mucus

14 Extended-release Tablets

AUROHEALTH

Top Layer Printing side

The top layer printing side of the box features a barcode on the left with the number 58602-71405. The main text includes the product name 'Mucus Relief DM', the active ingredients 'Dextromethorphan HBr and Guaifenesin', and the dosage 'Extended-release Tablets 30 mg/600 mg'. It also states 'Dextromethorphan HBr 30 mg - Cough Suppressant' and 'Guaifenesin 600 mg - Expectorant'. A green banner at the bottom says 'RELIEVES COUGH & CHEST CONGESTION'. There is a 'PARENTS' warning box with the text 'Learn about teen medicine abuse' and 'www.StopMedicineAbuse.org'. The distributor information is 'AUROHEALTH LLC, 279 Princeton-Hightstown Road, East Windsor, NJ 08520'. It also says 'Made in India'. A 'Lift Here for Drug Facts' label is on the right. A tamper-evident seal is shown with the text 'Tamper evident: Do not use if seal over bottle opening is broken or missing'. A dashed line indicates an 'Unvarnished Zone (dotted line not for printing) 40 x 15 mm'. The lot number 'P1435222' is printed.

*Lot: XXXXXXXX
Exp.: YYYY-MMM
Prefix, Variables of Lot, Exp and
Neutral code shall be
printed online during packing.

Top Layer Adhesive side

The top layer adhesive side of the box features a 'Drug Facts' label. The label includes the following information: 'Active Ingredients (in each extended-release tablet)' with 'Dextromethorphan Hydrobromide USP 30 mg' and 'Guaifenesin USP 600 mg'. 'Purposes' are listed as 'Cough suppressant' and 'Expectorant'. 'Uses' are listed as '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', and 'the impulse to cough to help you get to sleep'. The lot number 'P1435222' is printed on the left. A 'Gluing Area' is indicated on the right.

2nd Layer Printing side

The 2nd layer printing side of the box features a 'Drugs Facts (Continued)' label. The label includes the following information: 'Warnings' with '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), and 'Lift Here' on the right.

Gluing Area	<p>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.</p> <p>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)</p> <p>When using this product ■ do not use more than directed</p> <p>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</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>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.</p>	P1435222

2nd Layer Adhesive side

Gluing Area	<p>Drugs Facts (Continued)</p> <p>Directions</p> <p>■ 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 or 2 extended-release tablets every 12 hours; not more than 4 extended-release tablets in 24 hours ■ children under 12 years of age: do not use</p> <p>Other Information</p> <p>■ store at 20° to 25°C (68° to 77°F)</p> <p>Inactive Ingredients</p> <p>colloidal silicon dioxide, hypromellose, magnesium stearate, microcrystalline cellulose, povidone, pregelatinized starch (maize)</p> <p>Questions? call 1-855-274-4122</p>	P1435222

Base Layer

Gluing Area	<p style="text-align: center;">NDC 58602-714-05</p> <p style="text-align: center;">Mucus Relief DM</p> <p style="text-align: center;">Dextromethorphan HBr and Guaifenesin</p> <p style="text-align: center;">Extended-release Tablets 30 mg/600 mg</p> <p style="text-align: center;">Dextromethorphan HBr 30 mg - Cough Suppressant Guaifenesin 600 mg - Expectorant</p> <p style="text-align: center;">RELIEVES COUGH & CHEST CONGESTION</p> <div style="text-align: center;">  </div> <div style="display: flex; justify-content: space-between;"> <div> <input checked="" type="checkbox"/> Controls Cough <input checked="" type="checkbox"/> Thins & Loosens Mucus </div> <div style="text-align: center;"> 14 Extended-release Tablets </div> </div> <p style="text-align: center;">AUROHEALTH</p>	<p>PARENTS: Learn about teen medicine abuse www.StopMedicineAbuse.org</p> <p>Distributed by: AUROHEALTH LLC 279 Princeton-Hightstown Road East Windsor, NJ 08520</p> <p>Made in India</p>	P1435222

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

Dextromethorphan HBr 30 mg - Cough Suppressant
Guaifenesin 600 mg - Expectorant

RELIEVES COUGH & CHEST CONGESTION

- ✓ Controls Cough
- ✓ Thins & Loosens Mucus

14 Extended-release Tablets

No Coating Area

Mucus Relief DM
Dextromethorphan HBr and Guafenesin
Extended-release Tablets 30 mg/600 mg

Drug Facts
Active Ingredients (in each extended-release tablet)
Dextromethorphan Hydrobromide USP 30 mg
Guafenesin USP 600 mg
Purposes
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
• Temporary relief:
• 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 extended-release tablet whole with a full glass of water with product can be administered without regard for timing of meals • adults and children 12 years and older: 1 or 2 extended-release tablets every 12 hours, not more than 4 extended-release tablets in 24 hours • children under 12 years of age: do not use

Other information
• Store at 20° to 25° (68° to 77°)
Inactive ingredients
carboxylic acid sodium, hydroxypropyl, magnesium stearate, microcrystalline cellulose, polyvinyl, pregelatinized starch (maize)

Questions? call 1-800-224-4322

Mucus Relief DM
Dextromethorphan HBr and Guafenesin
Extended-release Tablets 30 mg/600 mg
RELIEVES COUGH & CHEST CONGESTION

Compare to the active ingredients of Mucinex® DM*
NDC 58602-714-05

Mucus Relief DM
Dextromethorphan HBr and Guafenesin
Extended-release Tablets 30 mg/600 mg
Dextromethorphan HBr 30 mg • Cough Suppressant
Guafenesin 600 mg • Expectorant
RELIEVES COUGH & CHEST CONGESTION

12 HOUR

62
ACTUAL SIZE

14 Extended-release Tablets

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PARENTS: Do not use if seal is broken or missing
Keep out of reach of children
See back of box for more information

Glue B2B

No Coating-Glue Area

No Coating Area

11097126
Unlaminated Zone
(shaded red not for printing)
80 x 31 mm

Compare to the active ingredients of Mucinex® DM*

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

Dextromethorphan HBr 30 mg - Cough Suppressant
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RELIEVES COUGH & CHEST CONGESTION

12
HOUR

- ✓ Controls Cough
- ✓ Thins & Loosens Mucus

ACTUAL SIZE

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
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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: 70097M6I3O)				
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)