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 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

- 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?

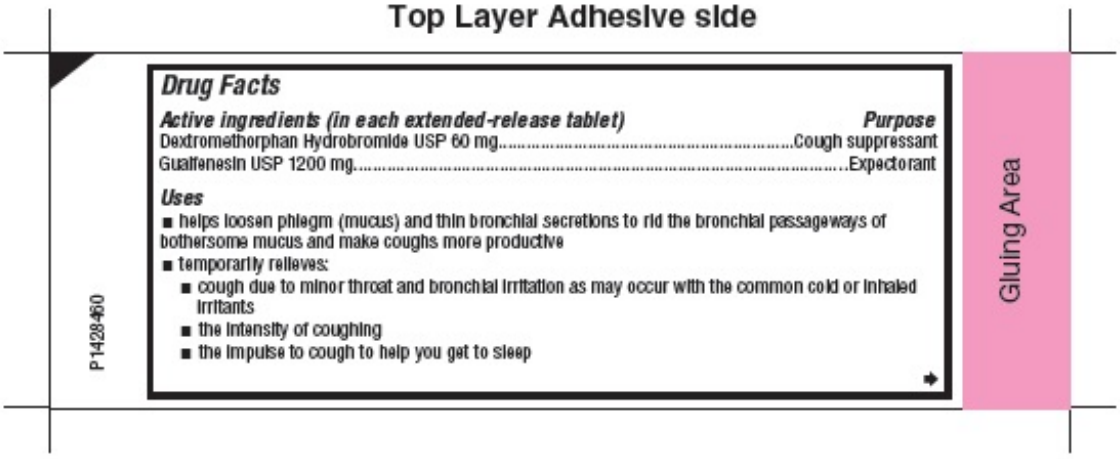
call **1-855-274-4122** You may also report side effects to this phone number.

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

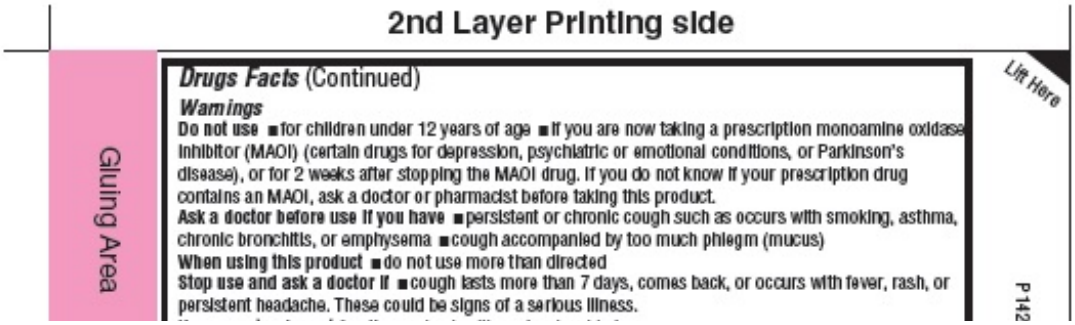
NDC 58602-715-05
MAXIMUM STRENGTH
Mucus Relief DM
Guaifenesin and Dextromethorphan HBr
Extended-release Tablets
1200 mg/60 mg
EXPECTORANT AND COUGH SUPPRESSANT
12 HOUR
Controls Cough
Thins and Loosens Mucus
14 Extended-release Tablets
AUROHEALTH

Top Layer Printing side

Top Layer Adhesive side



2nd Layer Printing side



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.

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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

Other information

■store at 20° to 25°C (68° to 77°F)

Inactive ingredients

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Gluing Area

Base Layer

Gluing Area

NDC 58602-715-05

MAXIMUM STRENGTH

Mucus Relief DM

Guaifenesin and Dextromethorphan HBr
Extended-release Tablets 1200 mg/60 mg

EXPECTORANT AND COUGH SUPPRESSANT

12 HOUR

Controls Cough
Thins and Loosens Mucus
14 Extended-release Tablets

AUROHEALTH

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

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

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

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

Compare to the active ingredients of
Maximum Strength Mucinex® DM*
NDC 58602-715-05
Mucus Relief DM
MAXIMUM STRENGTH
Guaifenesin and Dextromethorphan HBr
Extended-release Tablets
1200 mg/60 mg
EXPECTORANT AND
COUGH SUPPRESSANT
12 HOUR
Controls Cough
Thins and Loosens Mucus
14 Extended-release Tablets
AUROHEALTH

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 1200 mg/60 mg Blister Carton 28 (4 x 7) Unit-dose Tablets

Comparative to the active ingredients of
Maximum Strength Mucinex® DM*
NDC 58602-715-70
MAXIMUM STRENGTH
Mucus Relief DM
Guaifenesin and
Dextromethorphan HBr
Extended-release Tablets
1200 mg/60 mg
EXPECTORANT AND
COUGH SUPPRESSANT
12 HOUR
Controls Cough
Thins and Loosens Mucus
28 (4 x7)
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:58602-715
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:58602-715-05	1 in 1 CARTON	03/17/2017	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:58602-715-57	1 in 1 CARTON	03/17/2017	
2		28 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:58602-715-09	1 in 1 CARTON	03/17/2017	
3		30 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:58602-715-68	1 in 1 CARTON	03/17/2017	
4		38 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:58602-715-60	1 in 1 CARTON	03/17/2017	
5		42 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:58602-715-69	1 in 1 CARTON	03/17/2017	
6		44 in 1 BOTTLE; Type 0: Not a Combination Product		
7	NDC:58602-715-15	1 in 1 CARTON	03/17/2017	
7		60 in 1 BOTTLE; Type 0: Not a Combination Product		
8	NDC:58602-715-70	4 in 1 CARTON	03/17/2017	
8		7 in 1 BLISTER PACK; Type 0: Not a Combination Product		
9	NDC:58602-715-06	6 in 1 CARTON	03/17/2017	
9		7 in 1 BLISTER PACK; Type 0: Not a Combination Product		
10	NDC:58602-715-65	2 in 1 CARTON	03/17/2017	

10		7 in 1 BLISTER PACK; Type 0: Not a Combination Product		
11	NDC:58602-715-10	6 in 1 CARTON	03/17/2017	
11		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		
12	NDC:58602-715-64	1 in 1 CARTON	03/17/2017	
12		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	03/17/2017	

Labeler - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(58602-715) , MANUFACTURE(58602-715)