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

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 extended-release tablet every 12 hours; not more than 2 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 - 1200 mg/60 mg (14 Tablet Bottle)

NDC 58602-715-05

MAXIMUM STRENGTH
Mucus Relief DM

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

Dextromethorphan HBr 60 mg - Cough Suppressant
Guaifenesin 1200 mg - Expectorant

RELIEVES COUGH & CHEST CONGESTION

12
HOUR

✓ Controls Cough
✓ Thins & Loosens Mucus

14 Extended-release Tablets

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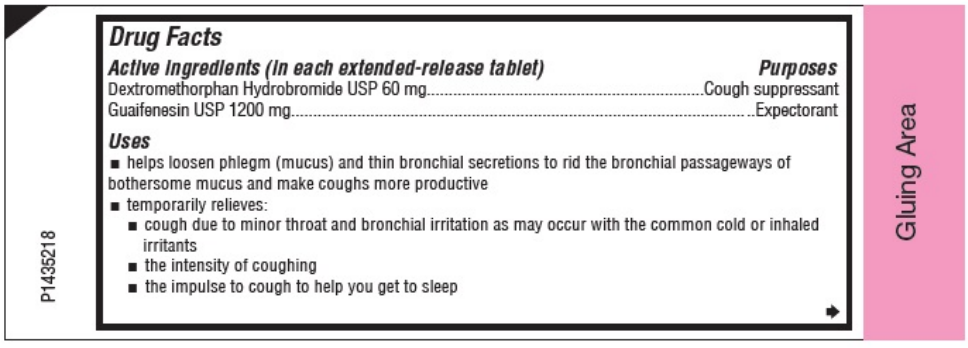
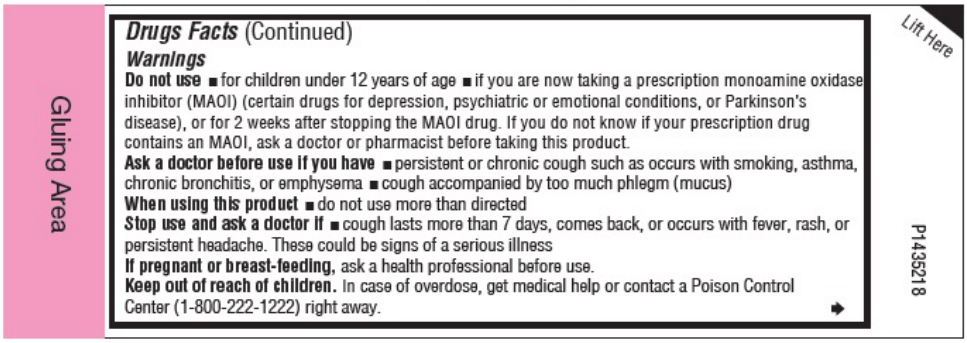
Top Layer Printing side

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

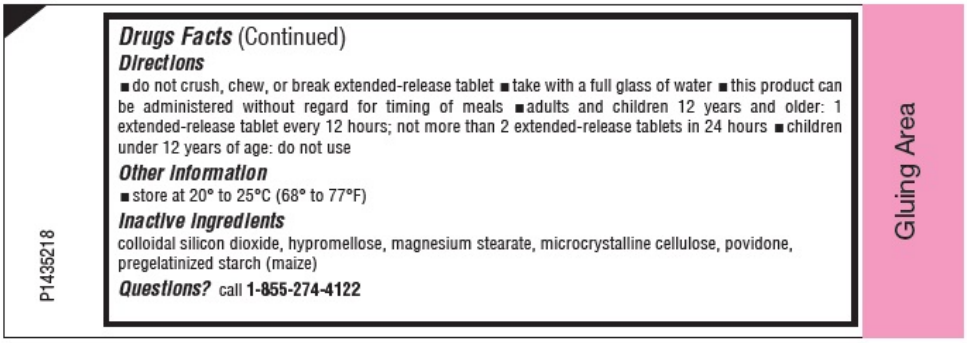
Top Layer Adhesive side



2nd Layer Printing side



2nd Layer Adhesive side



Base Layer

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

MAXIMUM STRENGTH
Mucus Relief DM

Dextromethorphan HBr

and Guaifenesin Extended-release Tablets
60 mg/1200 mg

Dextromethorphan HBr 60 mg - Cough Suppressant
Guaifenesin 1200 mg - Expectorant

RELIEVES COUGH & CHEST CONGESTION

12
HOUR

√ Controls Cough
√ Thins and Loosens Mucus

ACTUAL SIZE

14 Extended-release Tablets

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

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

NDC 58602-715-70

MAXIMUM STRENGTH
Mucus Relief DM

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

Dextromethorphan HBr 60 mg - Cough Suppressant
Guaifenesin 1200 mg - Expectorant

RELIEVES COUGH & CHEST CONGESTION

12
HOUR

√ **Controls Cough**
√ **Thins & Loosens Mucus**

ACTUAL SIZE

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)

Revised: 10/2024 Aurohealth LLC