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



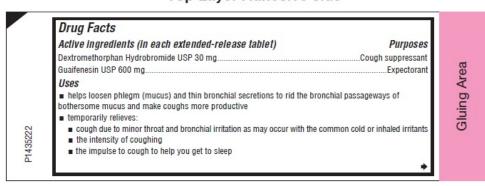
Neutral code shall be printed online during packing.

*Lot: XXXXXXXXXX

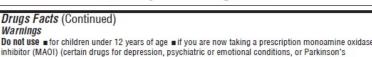
Exp.: YYYY-MMM

Prefix, Variables of Lot, Exp and

Top Layer Adhesive side



2nd Layer Printing side





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 me persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema mecough accompanied by too much phlegm (mucus)

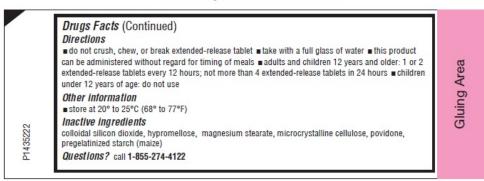
When using this product medo not use more than directed

Stop use and ask a doctor if a 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.

2nd Layer Adhesive side



Base Layer



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

12 HOUR

√ Controls Cough

√ Thins & Loosens Mucus

ACTUAL SIZE

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 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

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

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	

	60 in 1 BOTTLE; Type 0: Not a Combination Product		
NDC:58602- 714-67	2 in 1 CARTON	03/17/2017	
NDC:58602- 714-03	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
NDC:58602- 714-08	4 in 1 CARTON	03/17/2017	
NDC:58602- 714-03	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
NDC:58602- 714-07	6 in 1 CARTON	03/17/2017	
NDC:58602- 714-03	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
	714-67 NDC:58602- 714-03 NDC:58602- 714-08 NDC:58602- 714-03 NDC:58602- 714-07 NDC:58602-	Product NDC:58602- 714-67 2 in 1 CARTON NDC:58602- 714-03 NDC:58602- 714-08 NDC:58602- 714-03 NDC:58602- 714-03 NDC:58602- 714-07 NDC:58602- 714-07 NDC:58602- 714-07 NDC:58602- 714-07 NDC:58602- 714-07 NDC:58602- 10 in 1 BLISTER PACK; Type 0: Not a Combination Product NDC:58602- 10 in 1 BLISTER PACK; Type 0: Not a Combination	Product NDC:58602- 714-67 2 in 1 CARTON NDC:58602- 714-03 NDC:58602- 714-08 4 in 1 CARTON NDC:58602- 714-03 NDC:58602- 714-07 NDC:58602- 714-07 10 in 1 BLISTER PACK; Type 0: Not a Combination Product 03/17/2017 03/17/2017 03/17/2017 03/17/2017

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: 10/2024 Aurohealth LLC