

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

Guaifenesin and Dextromethorphan HBr Extended-Release Tablets, 600 mg/30 mg

EXPECTORANT & COUGH SUPPRESSANT

Drug Facts

Active ingredient(s)
(in each extended-release tablet)

Active ingredient (in each extended-release tablet)

Dextromethorphan HBr 30 mg

Guaifenesin 600 mg

Purpose

Guaifenesin - Expectorant

Dextromethorphan HBr - Cough suppressant

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 right away. (1-800-222-1222)

Directions

600 mg/30 mg

- 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

- **Bottle: Tamper evident: Do not use if carton is open or if printed foil under cap is broken or missing**
- **Blister: Do not use if carton is open or if printed seal with product name on blister is broken or missing**
- store between 20° to 25°C (68° to 77°F)

Inactive ingredients

carbomer, colloidal silicon dioxide, D&C yellow #10 aluminum lake, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone and talc

Questions?

1-877-835-5472

You may also report side effects to this phone number.

Parents:

Learn about teen medicine abuse
www.StopMedicineAbuse.org

**Keep the carton. It contains important information.
See end panel for expiration date.**

†Mucinex® is a registered trademark of Reckitt Benckiser LLC.

Distributed by:

Amneal Pharmaceuticals LLC

Bridgewater, NJ 08807

Rev. 02-2018-00

Principal Display Panel

**Guaifenesin and Dextromethorphan HBr
Extended-Release Tablet
600 mg/30 mg**

PUSH TABLET THROUGH FOIL

Distributed by: Amneal Pharmaceuticals LLC
Bridgewater, NJ 08807

LOT
EXP

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LOT
EXP

†Compare to the active ingredients of Mucinex® DM

NDC 65162-038-03

Guaifenesin and Dextromethorphan HBr Extended-Release Tablets

600 mg/30 mg

EXPECTORANT & COUGH SUPPRESSANT



30 Extended-Release Tablets



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Dist. by: Amneal Pharmaceuticals LLC, Bridgewater, NJ 08807 Rev. 02-2018-00



Non-Varnish Area

**Guaifenesin and
Dextromethorphan HBr
Extended-Release Tablets**

600 mg/30 mg

**EXPECTORANT AND
COUGH SUPPRESSANT**

[†]Compare to the active ingredients of Mucinex[®] DM
NDC 65162-038-03

**Guaifenesin and
Dextromethorphan HBr
Extended-Release Tablets**

600 mg/30 mg

**EXPECTORANT AND
COUGH SUPPRESSANT**



AN038

- ✓ Controls Cough
 - ✓ Thins And Loosens Mucus
- 30 Extended-Release Tablets**



Drug Facts

Active ingredient (in each extended-release tablet)	Purpose
Dextromethorphan HBr 30 mg...	Cough suppressant
Guaifenesin 600 mg.....	Expectorant

Uses

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Drug Facts (continued)

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Drug Facts (continued)

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Bridgewater, NJ 08807 Rev. 02-2018-00



1.5" x 1.5"
Non-Varnish Area



GUAIFENESIN AND DEXTROMETHORPHAN HBR			
guaifenesin and dextromethorphan hbr tablet, extended release			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65162-038
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
	POVIDONE (UNII: FZ989GH94E)		
	CARBOMER HOMOPOLYMER TYPE A (UNII: F68VH75CJC)		

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	yellow (light yellow)	Score	no score
Shape	OVAL	Size	16mm
Flavor		Imprint Code	AN038
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65162-038-17	2 in 1 CARTON	11/01/2018	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:65162-038-03	1 in 1 CARTON	11/01/2018	
2		30 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:65162-038-06	1 in 1 CARTON	11/01/2018	
3		60 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA209692	11/01/2018	

Labeler - Amneal Pharmaceuticals LLC (123797875)

Establishment

Name	Address	ID/FEI	Business Operations
Amneal Pharmaceuticals of New York, LLC		123797875	analysis(65162-038) , label(65162-038) , manufacture(65162-038) , pack(65162-038)

Revised: 10/2024

Amneal Pharmaceuticals LLC