

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

-----  
**Guaifenesin and Dextromethorphan HBr Extended-Release Tablets, 1200 mg/60 mg**

**EXPECTORANT & COUGH SUPPRESSANT**

***Drug Facts***

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

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

Dextromethorphan HBr 60 mg

Guaifenesin 1200 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**

1200 mg/60 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 tablet every 12 hours; not more than 2 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](http://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. 04-2018-01

**Principal Display Panel**

**Maximum Strength  
Guaifenesin and Dextromethorphan HBr  
Extended-Release Tablet  
1200 mg/60 mg**

**PUSH TABLET THROUGH FOIL**

Distributed by: Amneal Pharmaceuticals LLC  
Bridgewater, NJ 08807

LOT  
EXP

**Maximum Strength  
Guaifenesin and Dextromethorphan HBr  
Extended-Release Tablet  
1200 mg/60 mg**

**PUSH TABLET THROUGH FOIL**

Distributed by: Amneal Pharmaceuticals LLC  
Bridgewater, NJ 08807

LOT  
EXP

**Maximum Strength  
Guaifenesin and Dextromethorphan HBr  
Extended-Release Tablet  
1200 mg/60 mg**

**PUSH TABLET THROUGH FOIL**

Distributed by: Amneal Pharmaceuticals LLC  
Bridgewater, NJ 08807

LOT  
EXP

**Maximum Strength  
Guaifenesin and Dextromethorphan HBr  
Extended-Release Tablet  
1200 mg/60 mg**

**PUSH TABLET THROUGH FOIL**

Distributed by: Amneal Pharmaceuticals LLC  
Bridgewater, NJ 08807

LOT  
EXP

**Maximum Strength  
Guaifenesin and Dextromethorphan HBr  
Extended-Release Tablet  
1200 mg/60 mg**

**PUSH TABLET THROUGH FOIL**

Distributed by: Amneal Pharmaceuticals LLC  
Bridgewater, NJ 08807

LOT  
EXP

**Maximum Strength  
Guaifenesin and Dextromethorphan HBr  
Extended-Release Tablet  
1200 mg/60 mg**

**PUSH TABLET THROUGH FOIL**

Distributed by: Amneal Pharmaceuticals LLC  
Bridgewater, NJ 08807

LOT  
EXP

**Maximum Strength  
Guaifenesin and Dextromethorphan HBr  
Extended-Release Tablet  
1200 mg/60 mg**

**PUSH TABLET THROUGH FOIL**

Distributed by: Amneal Pharmaceuticals LLC  
Bridgewater, NJ 08807

LOT  
EXP

**Maximum Strength  
Guaifenesin and Dextromethorphan HBr  
Extended-Release Tablet  
1200 mg/60 mg**

**PUSH TABLET THROUGH FOIL**

Distributed by: Amneal Pharmaceuticals LLC  
Bridgewater, NJ 08807

LOT  
EXP

**Maximum Strength  
Guaifenesin and Dextromethorphan HBr  
Extended-Release Tablet  
1200 mg/60 mg**

**PUSH TABLET THROUGH FOIL**

Distributed by: Amneal Pharmaceuticals LLC  
Bridgewater, NJ 08807

LOT  
EXP

**Maximum Strength  
Guaifenesin and Dextromethorphan HBr  
Extended-Release Tablet  
1200 mg/60 mg**

**PUSH TABLET THROUGH FOIL**

Distributed by: Amneal Pharmaceuticals LLC  
Bridgewater, NJ 08807

LOT  
EXP

## MAXIMUM STRENGTH

<sup>†</sup>Compare to the active ingredients of MAXIMUM STRENGTH Mucinex<sup>®</sup> DM  
NDC 65162-039-03

# Guaifenesin and Dextromethorphan HBr Extended-Release Tablets

1200 mg/60 mg

EXPECTORANT & COUGH  
SUPPRESSANT



AND39

30 Extended-Release Tablets



### 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

### Parents:

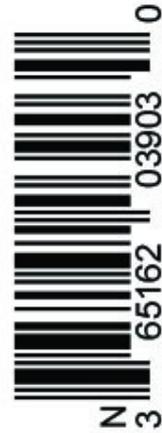
Learn about teen medicine abuse  
[www.StopMedicineAbuse.org](http://www.StopMedicineAbuse.org)

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

<sup>†</sup>Mucinex<sup>®</sup> is a registered trademark of Reckitt Benckiser LLC.

Distributed by: **Amneal Pharmaceuticals LLC**  
Bridgewater, NJ 08807

Rev. 04-2018-01



Non-Varnish Area



# GUAIFENESIN AND DEXTROMETHORPHAN HBR

guaifenesin and dextromethorphan hbr tablet, extended release

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:65162-039
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	1200 mg
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	60 mg

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>CARBOMER HOMOPOLYMER TYPE A</b> (UNII: F68VH75CJC)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	

**Product Characteristics**

<b>Color</b>	yellow (light yellow)	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	22mm
<b>Flavor</b>		<b>Imprint Code</b>	AN039
<b>Contains</b>			

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:65162-039-17	2 in 1 CARTON	11/01/2018	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:65162-039-03	1 in 1 CARTON	11/01/2018	
2		30 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:65162-039-06	1 in 1 CARTON	11/01/2018	
3		60 in 1 BOTTLE; Type 0: Not a Combination Product		

**Marketing Information**

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

**Labeler** - Amneal Pharmaceuticals LLC (123797875)**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Amneal Pharmaceuticals of New York, LLC		123797875	analysis(65162-039) , label(65162-039) , manufacture(65162-039) , pack(65162-039)

Revised: 12/2023

Amneal Pharmaceuticals LLC