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

Guaifenesin and Dextromethorpham 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

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

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Bridgewater, NJ 08807

LOT
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MAXIMUM STRENGTH

†Compare to the active ingredients of MAXIMUM STRENGTH Mucinex® DM

NDC 65162-039-03

Guaifenesin and Dextromethorphan HBr Extended-Release Tablets

1200 mg/60 mg

EXPECTORANT & COUGH SUPPRESSANT

12 HOUR

AN039

30 Extended-Release Tablets

amneal

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Rev. 04-2018-01

N 3 65162 03903 0

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:65162-039
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
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)	
POVIDONE (UNII: FZ989GH94E)	

Product Characteristics

Color	yellow (light yellow)	**Score**	no score
Shape	OVAL	**Size**	22mm
Flavor		**Imprint Code**	AN039
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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

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(65162-039) , label(65162-039) , manufacture(65162-039) , pack(65162-039)

Revised: 12/2022 Amneal Pharmaceuticals LLC