

GUAIFENESIN DM- guaifenesin and dextromethorphan hydrobromide tablet
PD-Rx Pharmaceuticals, Inc.

Drug Facts

Active ingredients (in each tablet)

Guaifenesin 400mg

Dextromethorphan HBr 20mg

Purpose

Expectorant

Cough suppressant

Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus
- helps make cough more productive
- temporarily relieves cough due to minor throat and bronchial irritation as may occur with a common cold

Warnings

Do not use

- 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 MAOI drug. If you do not know whether your prescription drug contains MAOI, ask your doctor or pharmacist before using 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 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

- take with a full glass of water
- this product can be administered without regard for the timing of meals
- do not exceed 6 doses in 24 hours or as directed by doctor

adults and children 12 years of age and over	take 1 tablet every 4 hours as needed
children 6 to under 12 years of age	take ½ tablet every 4 hours as needed
children under 6 years of age	consult a doctor

Other information

- store at room temperature 15°-30°C (59°-86°F)

Inactive ingredients

magnesium stearate, maltodextrin, microcrystalline cellulose, povidone, silicon dioxide, stearic acid.

Questions?

Adverse drug event call (866) 562-2756

Drug Facts	
Active Ingredient (in each tablet)	Purpose
Guaifenesin 400 mg.....Expectorant	
Dextromethorphan HBr 20 mg.....Cough Suppressant	
Uses:	
<ul style="list-style-type: none"> Helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus Helps make cough more productive Temporarily relieves cough due to minor throat and bronchial irritation as may occur with a common cold 	
Warnings:	
<p>Do not use, 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 MAOI drug. If you do not know whether your prescription drug contains an MAOI, ask your doctor or pharmacist before using this product.</p>	
Ask doctor before use if you have:	
<ul style="list-style-type: none"> persistent or chronic cough, such as occurs with smoking, asthma, chronic bronchitis or emphysema cough accompanied by too much phlegm (mucus) 	
Stop use and ask a doctor if:	
<ul style="list-style-type: none"> cough lasts more than 7 days, comes back, or occurs with fever, rash, or persistent headache. <p>These could be signs of serious illness.</p>	
If pregnant or breast feeding ask a health professional before use.	

NDC 43063-801-30



Immediate Release
Expectorant • Cough Suppressant

Guaifenesin - DM

guaifenesin 400mg & Dextromethorphan HBr 20mg



3 43063 80130 7

30 Tablets
TAMPER EVIDENT. DO NOT USE IF SEAL IS BROKEN OR MISSING FROM BOTTLE.

Drug Facts (continued)	
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (800) 222-1222.	
Direction:	
<ul style="list-style-type: none"> take with a full glass of water • this product can be administered without regard for the timing of meals do not exceed 6 doses in 24 hours or as directed by doctor 	
Adults and children 12 years of age and over	take 1 tablet every 4 hours as needed
Children 6 to 12 years of age	take 1/2 tablet every 4 hours as needed
Children under 6 years of age	consult a doctor
When using this product • do not use more than directed	
Other information:	
• store at room temperature 15°-30°C (59°-86°F)	
Inactive Ingredients: magnesium stearate, maltodextrin, microcrystalline cellulose, povidone, silicon dioxide, stearic acid.	
Questions? Adverse drug event call: (866) 562-2756	
Marketed and Packaged By: PD-Rx Pharmaceuticals, Inc Oklahoma City, OK 73127 Phone 1-405-942-3040	
GTIN: 00343063801307	SNO: A23C40000006
EXP: 05/2025	LOT: A23C40
	V.10.19.0

GUAIFENESIN DM

guaifenesin and dextromethorphan hydrobromide tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43063-801(NDC:16103-381)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg

Inactive Ingredients

Ingredient Name	Strength
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	white	Score	2 pieces
Shape	CAPSULE (CAPSULE SHAPED TABLET)	Size	18mm
Flavor		Imprint Code	PH073
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43063-801-90	90 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/02/2018	11/30/2027
2	NDC:43063-801-60	60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/02/2018	11/30/2027
3	NDC:43063-801-30	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/02/2018	11/30/2027

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	04/02/2018	11/30/2027

Labeler - PD-Rx Pharmaceuticals, Inc. (156893695)

Registrant - PD-Rx Pharmaceuticals, Inc. (156893695)

Establishment

Name	Address	ID/FEI	Business Operations
PD-Rx Pharmaceuticals, Inc.		156893695	repack(43063-801)

Revised: 10/2023

PD-Rx Pharmaceuticals, Inc.