

PHARBINEX-DM- guaifenesin 400mg and dextromethorphan hbr 20mg tablet
Pharbest Pharmaceuticals, Inc.

Pharbinex DM Tablet

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)

Inactive ingredients

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

Questions?

Adverse drug event call (866) 562-2756 Mon-Fri: 8 AM to 4 PM

PHARBEST

NDC 16103-381-04

Manufactured in the USA

Immediate Release

***Compare to the active ingredient in MUCINEX® DM Tablets**

PHARBINEX-DM

Guaifenesin 400mg & Dextromethorphan HBr 20mg

Expectorant & Cough Suppressant

30 TABLETS

RETAIN CARTON FOR COMPLETE PRODUCT INFORMATION

TAMPER EVIDENT: DO NOT USE IF SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

OMIT C

PHARBEST
NDC 16103-381-04

Immediate Release *COMPARE TO the active ingredient in MUCINEX[®] DM Tablets

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Guafenesin 400mg & Dextromethorphan HBr 20mg

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NDC 16103-381-04

Immediate Release

PHARBINEX-DM

Guafenesin 400mg & Dextromethorphan HBr 20mg

Expectorant & Cough Suppressant

30 TABLETS 

Manufactured By:
Pharmacia Corporation
14 Engineers Lane, Farmingdale, NY 11735

Rev. 03/19

Drug Facts (continued)

- 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

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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 1/2 tablet every 4 hours as needed
 children under 6 years of age consult a doctor

Other information

- store at room temperature (15°-30°C)

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

Questions? Adverse drug event call
 (866) 562-2756 Mon-Fri: 9 AM to 4 PM

*This product is not manufactured or distributed by Heckit Benckiser LLC, owner of registered trademark Mucinex[®].

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PHARBINEX-DM			
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Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	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:16103-381-04	1 in 1 CARTON	04/02/2018	
1		30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M	04/02/2018	

Labeler - Pharbest Pharmaceuticals, Inc. (557054835)

Establishment

Name	Address	ID/FEI	Business Operations
Pharbest Pharmaceuticals, Inc.		557054835	manufacture(16103-381) , analysis(16103-381) , pack(16103-381) , label(16103-381)