

PHARBINEX-DM- guaifenesin 400mg and dextromethorphan hbr 20mg tablet Ulai Health LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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

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 the MAOI drug. If you do not know whether your prescription drug contains an 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 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

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

Other information

store at 20^o- 25^oC (68^o-77^oF)

Inactive ingredients

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

Questions or comments?

(866) 562-2756 (Mon-Fri 8 AM to 4 PM EST)

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

*This product is not manufactured or distributed by Reckitt Benckiser LLC, owner of registered trademark Mucinex®

Distributed by:

ULAI HEALTH LLC.

Alexandria, VA 22312

PHARBEST

NDC 73057-381-04

Manufactured in the USA

Immediate Release

PHARBINEX-DM

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

Guaifenesin 400mg

Dextromethorphan HBr 20mg

Expectorant &

Cough Suppressant

30 TABLETS

Drug Facts (continued)

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

- take with a full glass of water. this product can be administered without regard for the timing of the meals. do not exceed 6 doses in 24 hours or as directed by a 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 1/2 tablet every 4 hours as needed
children under 6 years of age	ask a doctor

Other information

- store at 20°-25° C (68°-77° F)

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

Questions or comments?
(866) 562-2756 (Mon-Fri 8 AM to 4 PM EST)

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STOP PEELING

PHARBINEX-DM

guaifenesin 400mg and dextromethorphan hbr 20mg tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73057-381
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 K30 (UNII: U725QWY32X)	
POVIDONE K90 (UNII: RDH86HJV5Z)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	white	Score	2 pieces
Shape	CAPSULE	Size	18mm
Flavor		Imprint Code	PH073
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73057-381-04	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/18/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/18/2019	

Labeler - Ulai Health LLC (081181535)

Revised: 1/2022

Ulai Health LLC