MUCUS RELIEF DM- dextromethorphan hbr and guaifenesin tablet TopCo Associates, 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 ingredient (in each tablet)

Dextromethorphan HBr 20 mg Guaifenesin 400 mg

Purpose

Cough suppressant Expectorant

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

• 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)

Ask a doctor or pharmacist before use if you are

taking sedatives or tranquilizers

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 accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

Adults and children 12 years and older: take 1 tablet every 4 hours with a full glass of water while symptoms persist. Do not exceed 6 doses in 24 hours.

Children under 12 years of age: do not use

Other Information

- store at 25°C (77°F) excursions between 15°-30°C (59°-86°F)
- keep in a dry place and do not expose to heat n do not use if imprinted safety seal under cap is broken or missing

Inactive Ingredients

croscarmellose sodium, maltodextrin, microcrystalline cellulose, povidone, silicon dioxide, stearic acid

Package/Label Principal Display Panel



100 TABLETS

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Cough suppressan

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Drug Facts (continued on inside

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Questions or Comments?

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dextromethorphan hbr and guaifenesin tablet

Product Information

Product Type HUMAN OTC DRUG **Item Code (Source)** NDC:76162-003

Route of Administration ORAL

Active Ingredient/Active Moiety

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

Inactive Ingredients	
Ingredient Name	Strength
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)	

Product Characte	oduct Characteristics				
Color	white	Score	2 pieces		
Shape	OVAL	Size	16mm		
Flavor		Imprint Code	AZ;345		
Contains					

ı	P	ackaging			
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1	NDC:76162-003- 01	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/23/2014	

Marketing In	Marketing Information		
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	12/23/2014	

Labeler - TopCo Associates, LLC (006935977)

Revised: 12/2018 TopCo Associates, LLC