

**MAXIMUM STRENGTH TUSSNEX FM DM MAX- dextromethorphan hbr,
guaifenesin liquid
Guardian Drug Company**

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.

Tussnex FM DM Max

Active ingredients (in each 20 mL)

Dextromethorphan HBr 20 mg

Guaifenesin 400 mg

Purpose

Cough suppressant

Expectorant

Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make coughs more productive
- temporarily relieves:
- cough due to minor throat and bronchial irritation as may occur with a 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 that occurs with 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 condition.

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.

Directions

- do not take more than 6 doses in any 24 hour period
- measure only with dosing cup provided
- do not use dosing cup with other products
- dose as follows or as directed by a doctor
- Adults & children 12 years & older: 20mL every 4 hours
- Children under 12 years of age: Do not use

Other information

- each 20 mL contains: potassium 20 mg, sodium 20 mg
- store between 15-30°C (59-86°F)
- do not refrigerate
- dosing cup provided

Inactive ingredients

citric acid anhydrous, D&C red 33, dextrose, FD&C red 40, flavors, glycerin, methylparaben, potassium sorbate, propylene glycol, propylparaben, purified water, saccharin sodium, sodium hydroxide, sorbitol, sucralose, xanthan gum

PDP

compare to active ingredients in Mucinex[®] Fast-Max[™]DM Max

Maximum strength

Tussnex FM DM Max

Dextromethorphan HBr

Cough suppressant

Guaifenesin

Expectorant

Multi-symptom

Relieves chest congestion

Thins and loosens mucus

Soothes cough

Dosing lasts 4 hours

For ages 12 & over



W 1.75" x H 3.25"

Drug Facts

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Guaifenesin 400 mg.....Expectorant

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PEEL HERE FOR CONTINUED DRUG FACTS ▶

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

*This product is not manufactured or distributed by Reckitt Benckiser, the distributor of Mucinex® Fast Max™ DM Max.

MFR#53041 REV0314

Guardian Drug Company
2 Charles Court
Dayton, NJ 08810

Drug Facts (continued)

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MAXIMUM STRENGTH TUSSNEX FM DM MAX

dextromethorphan hbr, guaifenesin liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53041-628
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 20 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg in 20 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
DEXTROSE (UNII: IY9XDZ35W2)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	red	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53041-628-58	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	05/01/2012	

Labeler - Guardian Drug Company (119210276)

Registrant - Guardian Drug Company (119210276)

Establishment

Name	Address	ID/FEI	Business Operations
Guardian Drug Company		119210276	manufacture(53041-628)

Revised: 1/2022

Guardian Drug Company