MAXI-TUSS GMX- dextromethorphan hydrobromide and guaifenesin liquid
MCR American Pharmaceuticals, Inc.

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.

Maxi-Tuss GMX

Drug Facts

Active Ingredients (in each 5 mL teaspoonful)	***Purpose***
Dextromethorphan HBr 10 mg	Cough Suppressant
Guaifenesin 200 mg	Expectorant

Uses

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 exceed recommended dosage.

Do not use this product

- 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)

Stop use and ask a doctor if

- cough lasts more than 7 days, comes back, or occurs with fever, rash or headache that lasts. 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 accidental overdose, seek professional help or contact a Poison Control Center immediately.

Directions

Do not exceed recommended dosage.

	2 teaspoonfuls (10 mL) every

Adults and children 12 years of age and over:	4 hours, not to exceed 12 teaspoonfuls in 24 hours or as directed by a doctor
Children 6 to under 12 years of age:	1 teaspoonful (5 mL) every 4 hours, not to exceed 6 teaspoonfuls in 24 hours or as directed by a doctor
Children under 6 years of age:	Consult a physician

Other information

Store at 59°-86°F (15°-30°C) [see USP Controlled Room Temperature]

Inactive ingredients

Cherry flavor, citric acid, methylparaben, monoammonium glycyrrhizinate, potassium citrate, propylparaben, propylene glycol, purified water, sorbitol, sucralose

Questions or comments?

Call 352.754.8587

Principal Display Panel - 473 mL Bottle Label

NDC 58605-312-16

Maxi-Tuss GMX
Cough Suppressant ■ Expectorant

Sugar Free ■ Alcohol Free ■ Dye Free

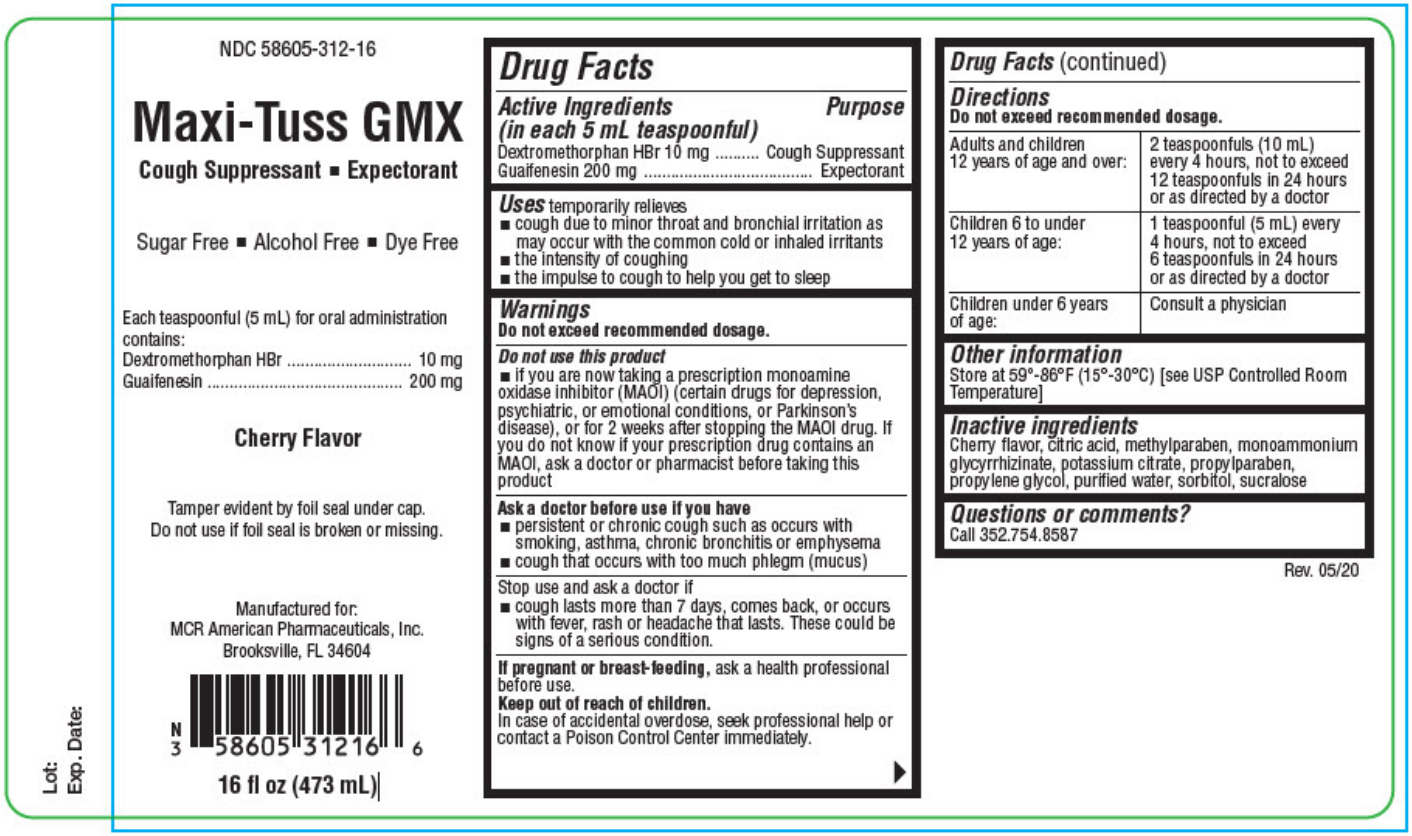
Each teaspoonful (5 mL) for oral administration
contains:
Dextromethorphan HBr 10 mg
Guaifenesin 200 mg

Cherry Flavor

Tamper evident by foil seal under cap.
Do not use if foil seal is broken or missing.

Manufactured for:
MCR American Pharmaceuticals, Inc.
Brooksville, FL 34604

16 fl oz (473 mL)



MAXI-TUSS GMX

dextromethorphan hydrobromide and guaifenesin liquid

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58605-312
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Dextromethorphan Hydrobromide (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	Dextromethorphan Hydrobromide	10 mg in 5 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
Methylparaben (UNII: A2I8C7HI9T)	
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)	
Potassium Citrate (UNII: EE90ONI6FF)	
Propylparaben (UNII: Z8IX2SC1OH)	
Propylene Glycol (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
Sorbitol (UNII: 506T60A25R)	

Sucralose (UNII: 96K6UQ3ZD4)	

Product Characteristics			
Color		**Score**	
Shape		**Size**	
Flavor	CHERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58605-312-16	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	08/01/2020	

Labeler - MCR American Pharmaceuticals, Inc. (783383011)

Establishment

Name	Address	ID/FEI	Business Operations
MCR American Pharmaceuticals, Inc.		783383011	MANUFACTURE(58605-312)

Revised: 6/2020 MCR American Pharmaceuticals, Inc.