MAXI-TUSS PE MAX- guaifenesin and phenylephrine hydrochloride 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 PE Max

Drug Facts

Active Ingredients (in each 5 mL teaspoonful)	***Purpose***
Guaifenesin 100 mg	Expectorant
Phenylephrine HCl 5 mg	Nasal Decongestant

Uses

temporarily relieves
- Nasal congestion due to the common cold
- Helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make coughs more productive

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
- heart disease
- thyroid disease
- high blood pressure
- diabetes
- difficulty in urination due to enlargement of the prostate gland
- 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
- nervousness, dizziness, or sleeplessness occur
- 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.

Adults and children 12 years of age and over:	2 teaspoonfuls (10 mL) every 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 doctor

Other information

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

Inactive ingredients

Citric acid, grape flavor, 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 58605-315-16

Maxi-Tuss PE Max

Expectorant Nasal Decongestant

Sugar Free Alcohol Free Dye Free

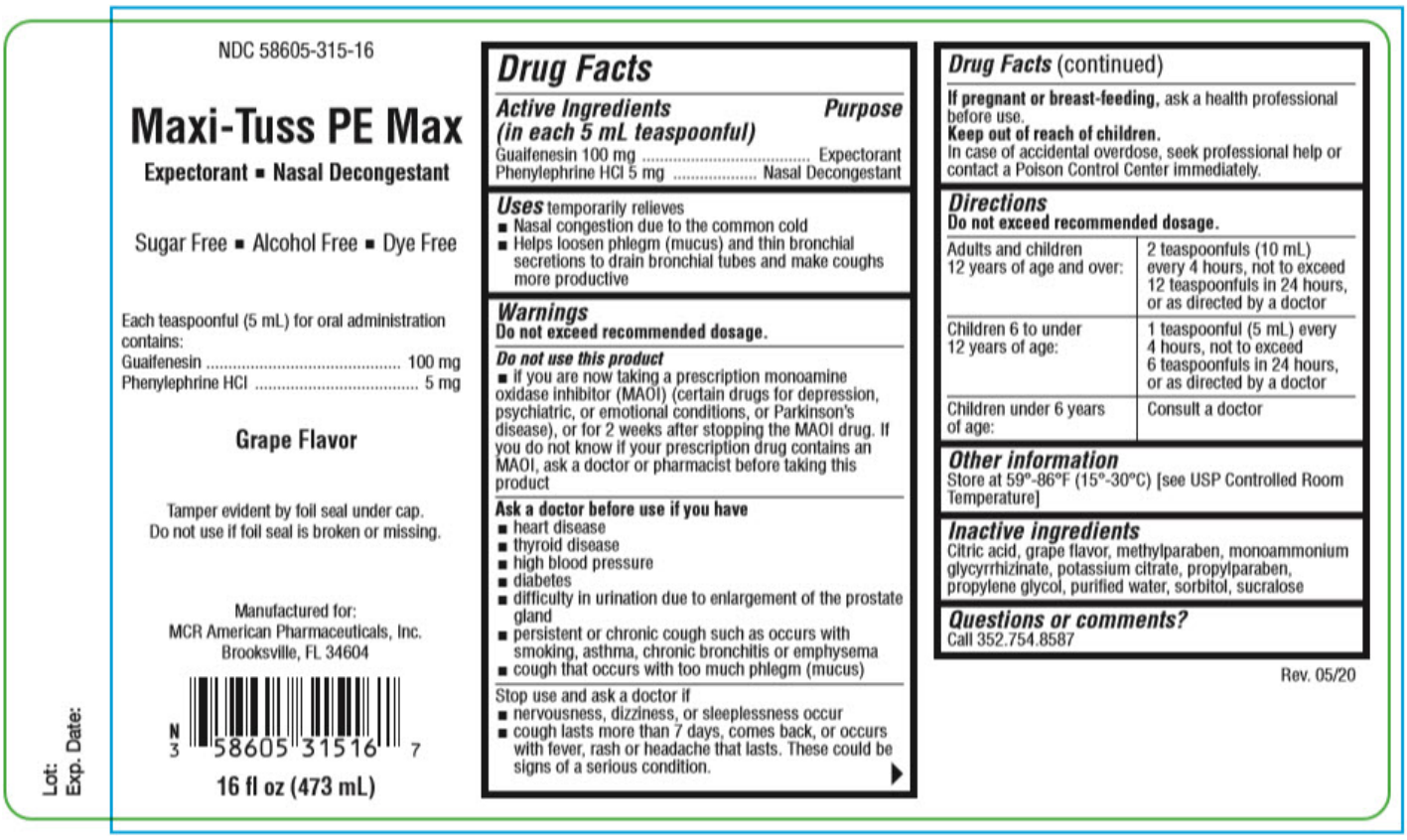
Each teaspoonful (5 mL) for oral administration
contains:
Guaifenesin 100 mg
Phenylephrine HCl 5 mg

Grape 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 PE MAX

guaifenesin and phenylephrine hydrochloride liquid

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58605-315
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL
Phenylephrine Hydrochloride (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	Phenylephrine Hydrochloride	5 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	GRAPE	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58605-315-16	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(58605-315)

Revised: 6/2020 MCR American Pharmaceuticals, Inc.