MAXI-TUSS PE- brompheniramine maleate 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

Drug Facts

Active Ingredients (in each 5 mL teaspoonful)	**Purpose**
Brompheniramine Maleate 2 mg	Antihistamine
Phenylephrine HCl 5 mg	Nasal Decongestant

Uses

temporarily relieves these symptoms due to the common cold, hay fever (allergic rhinitis) or other respiratory allergies:

- runny nose
- sneezing
- itching of the nose or throat
- itchy, watery eyes
- nasal congestion
- reduces swelling of nasal passages

Warnings

Do not exceed recommended dosage.

Do not take 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

- a breathing problem such as emphysema or chronic bronchitis
- glaucoma
- heart disease
- high blood pressure
- thyroid disease
- diabetes mellitus
- difficulty in urination due to enlargement of the prostate gland

Ask a doctor before use if you are taking sedatives or tranquilizers.

When using this product

- excitability may occur, especially in children
- may cause drowsiness
- sedatives and tranquilizers may increase drowsiness effect
- avoid alcoholic beverages

- use caution when driving a motor vehicle or operating machinery

Stop use and ask doctor if

- nervousness, dizziness, or sleeplessness occur
- If symptoms do not improve within 7 days or are accompanied by fever, consult a doctor
- new symptoms occur

If pregnant or breastfeeding, 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 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 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 for Controlled Room Temperature].

Inactive ingredients

Bubblegum flavor, citric acid, FD&C Red #40, methylparaben, potassium citrate, propylene glycol, propylparaben, purified water, sorbitol, sucralose

Questions or Comments?

Call 352.754.8587

PRINCIPAL DISPLAY PANEL - 473 mL Bottle Label

NDC 58605-306-16

Maxi-Tuss PE

Antihistamine • Nasal Decongestant

Sugar Free • Alcohol Free
• Gluten Free

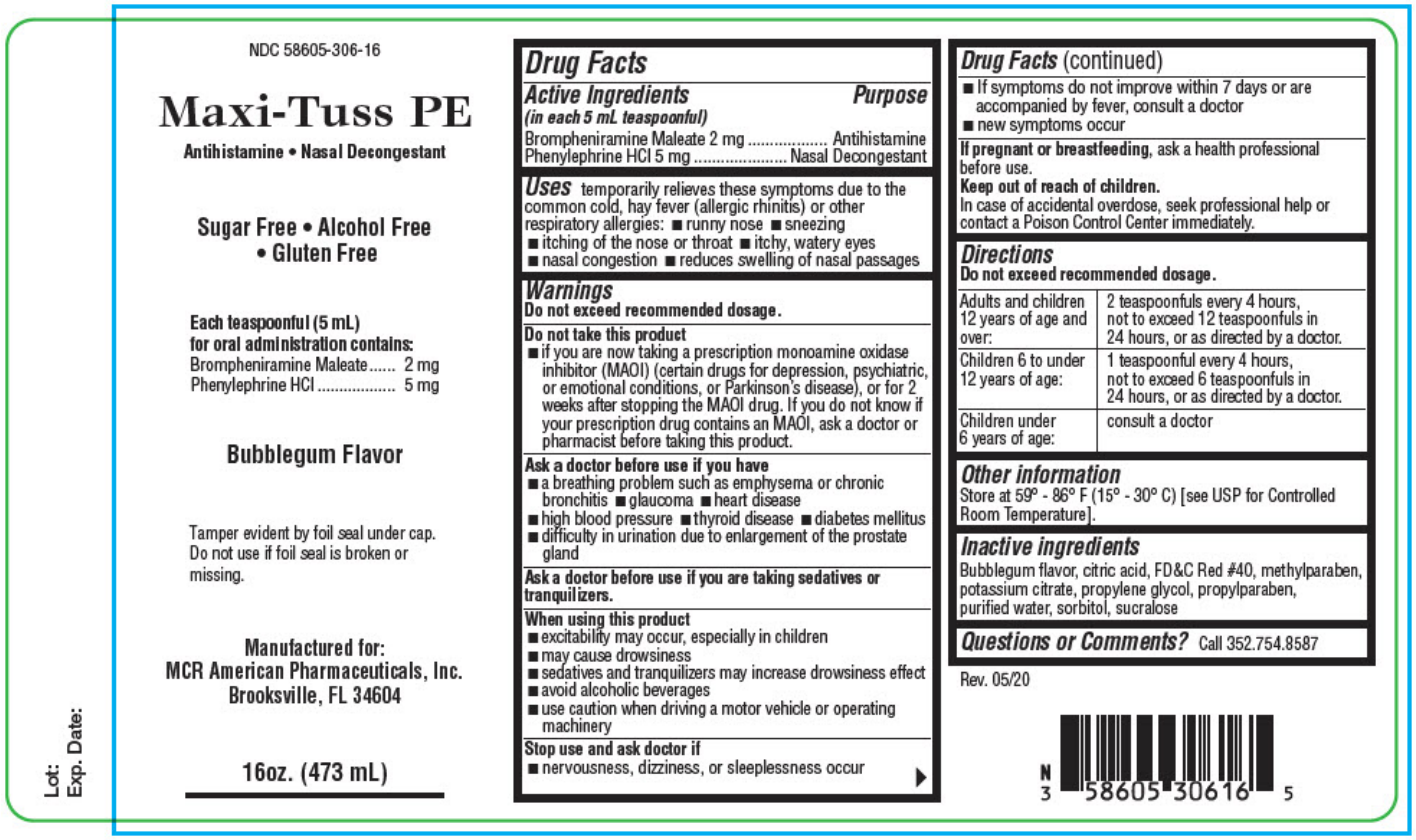
Each teaspoonful (5 mL)
for oral administration contains:
Brompheniramine Maleate 2 mg
Phenylephrine HCl 5 mg

Bubblegum 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

16oz. (473 mL)



MAXI-TUSS PE

brompheniramine maleate and phenylephrine hydrochloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58605-306
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BROMPHENIRAMINE MALEATE (UNII: IXA7C9ZN03) (BROMPHENIRAMINE - UNII:H57G17P2FN)	BROMPHENIRAMINE MALEATE	2 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)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
Methylparaben (UNII: A2I8C7HI9T)	
Potassium Citrate (UNII: EE90ONI6FF)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Propylparaben (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
Sorbitol (UNII: 506T60A25R)	
Sucralose (UNII: 96K6UQ3ZD4)	

Product Characteristics			
Color	PINK	**Score**	
Shape		**Size**	
Flavor	BUBBLE GUM	**Imprint Code**	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58605-306-16	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(58605-306)

Revised: 6/2020 MCR American Pharmaceuticals, Inc.