MAXI-TUSS CD- chlorpheniramine maleate, codeine phosphate, 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 CD

Drug Facts

Active Ingredients (in each 5 mL teaspoonful)	***Purpose***
Chlorpheniramine Maleate 4 mg	Antihistamine
Codeine Phosphate 10 mg	Cough Suppressant
Phenylephrine HCl 10 mg	Nasal Decongestant

Uses

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

- cough due to minor throat and bronchial irritation
- runny nose
- sneezing
- itching of the nose or throat
- itchy, watery eyes
- nasal congestion
- reduces swelling of nasal passages
- calms the cough control center and relieves coughing

Warnings

- **Do not exceed recommended dosage.**
- A persistent cough may be a sign of a serious condition. If cough persists for more than 1 week, tends to recur, or is accompanied by fever, rash, or persistent headache, consult a doctor.
- Adults and children who have a chronic pulmonary disease or shortness of breath, or children who are taking other drugs, should not take this product unless directed by a doctor.

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

- a persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema, or where cough is accompanied by excessive phlegm
- 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 marked drowsiness
- alcohol, sedatives and tranquilizers may increase drowsiness
- avoid alcoholic beverages
- use caution when driving a motor vehicle or operating machinery
- may cause or aggravate constipation

Stop use and ask a doctor if
- nervousness, dizziness, or sleeplessness occur
- if symptoms do not improve within 7 days or are accompanied by fever, consult a doctor

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:	1 teaspoonful every 4 hours, not to exceed 6 teaspoonfuls in 24 hours, or as directed by a doctor
Children 6 to under 12 years of age:	½ teaspoonful every 4 hours, not to exceed 3 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)

Inactive ingredients

Citric acid, flavor, methylparaben, potassium citrate, potassium sorbate, propylparaben, propylene glycol, purified water, sorbitol, sucralose

Questions or Comments?

Call (352) 754-8587

PRINCIPAL DISPLAY PANEL - 473 mL Bottle Label

NDC 58605-303-16

Maxi-Tuss CD

Antihistamine Cough Suppressant
Nasal Decongestant

CV

Each teaspoonful (5 mL) contains:
Chlorpheniramine Maleate 4 mg
Codeine Phosphate 10 mg
Phenylephrine HCl 10 mg

Grape Flavor

Alcohol Free Gluten Free Sugar Free

Caution: For manufacturing, processing, or repackaging. This is a bulk container; not intended for household use.

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

Lot:
Exp Date:

16 fl oz (473 mL)

NDC 58605-303-16

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Antihistamine ▪ Cough Suppressant
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N 3 58605 30316 4

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Drug Facts (continued)

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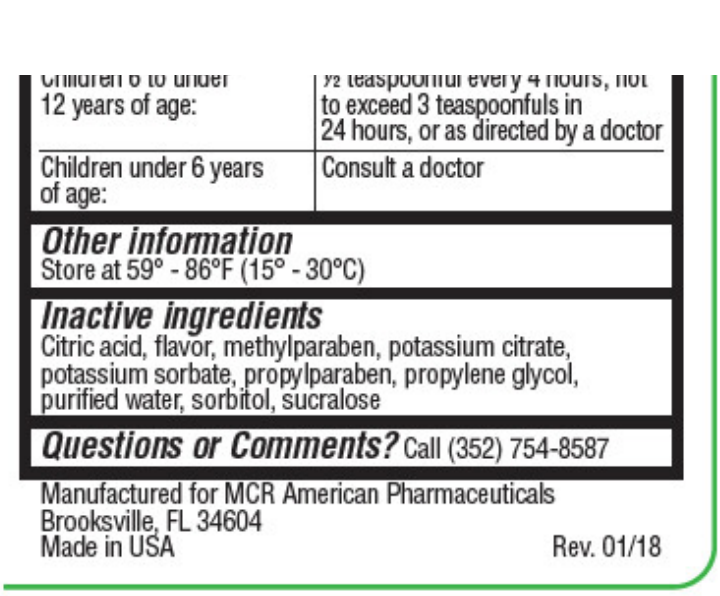
Children 6 to under	½ teaspoonful every 4 hours, not



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Questions or Comments? Call (352) 754-8587

Manufactured for MCR American Pharmaceuticals
Brooksville, FL 34604
Made in USA

Rev. 01/18

MAXI-TUSS CD

chlorpheniramine maleate, codeine phosphate, and phenylephrine hydrochloride liquid

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58605-303
Route of Administration	ORAL	**DEA Schedule**	CV

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	4 mg in 5 mL
CODEINE PHOSPHATE (UNII: GSL05Y1MN6) (CODEINE ANHYDROUS - UNII:UX6OWY2V7J)	CODEINE PHOSPHATE	10 mg in 5 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
Methylparaben (UNII: A2I8C7HI9T)	
Potassium Citrate (UNII: EE90ONI6FF)	
Potassium Sorbate (UNII: 1VPU26JZZ4)	
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:58605-303-16	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/01/2018	
2	NDC:58605-303-10	10 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	04/01/2018	

Labeler - MCR American Pharmaceuticals, Inc. (783383011)

Establishment

Name	Address	ID/FEI	Business Operations
MCR American Pharmaceuticals, Inc.		783383011	MANUFACTURE(58605-303)

Revised: 8/2019 MCR American Pharmaceuticals, Inc.