WESTUSSIN DM- dexchlorpheniramine maleate, dextromethorphan hbr, phenylephrine hcl syrup
Westminster Pharmaceuticals, LLC

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.

WesTussin DM

Drug Facts

Active ingredients (in each 5 mL teaspoonful)	***Purpose***
Dexchlorpheniramine Maleate 1 mg	Antihistamine
Dextromethorphan HBr 10 mg	Cough Suppressant
Phenylephrine HCl 5 mg	Nasal Decongestant

Uses

- temporarily relieves cough due to minor throat and bronchial irritation occurring with a cold or inhaled irritants
- temporarily relieves nasal congestion due to the common cold, hay fever or other respiratory allergies
- temporarily relieves these symptoms due to hay fever (allergic rhinitis):
- runny nose
- sneezing
- itching of the nose of throat
- itchy, watery eyes
- temporarily restores freer breathing through the nose

Warnings

Do not use 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
- high blood pressure
- thyroid disease
- diabetes
- a breathing problem such as emphysema or chronic bronchitis
- glaucoma
- difficulty in urination due to enlarged prostate gland

- persistent or chronic cough such as occurs with smoking, asthma or emphysema
- cough accompanied by excessive phlegm (mucus)

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

When using this product
- **do not exceed recommended dosage**
- marked drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase the drowsiness effect
- avoid alcoholic beverages
- use caution when driving a motor vehicle or operating machinery
- excitability may occur especially in children

Stop use and ask a doctor if
- cough persists for more than 1 week, tends to recur, or is accompanied by fever, rash or persistent headache. A persistent cough may be a sign of a serious condition.
- symptoms do not improve within 7 days or are accompanied by fever
- nervousness, dizziness, or sleeplessness occur

If pregnant or breastfeeding 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

Adults 12 and over:	10 mL every 4 hours Not to exceed 60 mL in 24hrs
Children 6-12:	5 mL every 4 hours Not to exceed 30 mL in 24hrs
Children 2-6:	Consult a doctor

Other information

Store at room temperature 15°C-30°C (59°F-86°F)

Inactive ingredients

Citric acid anhydrous, cotton candy flavoring, glycerin, propylene glycol, purified water, sodium benzoate, sodium citrate dihydrate, sorbitol solution, sucralose.

Questions?

Call weekdays from 9 AM to 5 PM EST at 1-844-221-7294. You may also report serious side effects to this phone number.

PRINCIPAL DISPLAY PANEL - 480 mL Bottle Label

NDC 69367-334-16

WesTussin DM

Antihistamine • Cough Suppressant
Nasal Decongestant
• Alcohol Free • Dye Free
• Sugar Free • Gluten Free

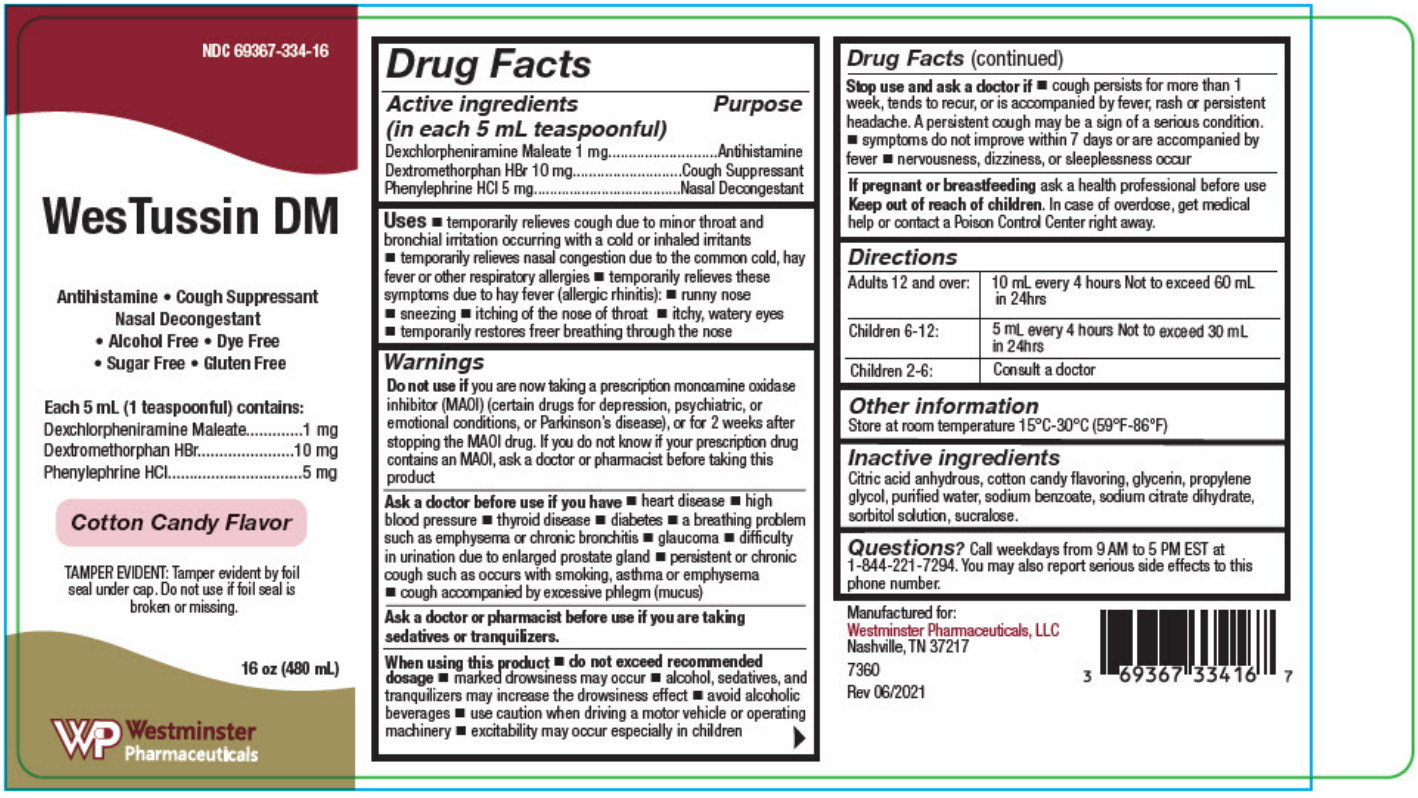
Each 5 mL (1 teaspoonful) contains:
Dexchlorpheniramine Maleate
1 mg
Dextromethorphan HBr
10 mg
Phenylephrine HCl
5 mg

Cotton Candy Flavor

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

16 oz (480 mL)

Westminster
Pharmaceuticals



WESTUSSIN DM

dexchlorpheniramine maleate, dextromethorphan hbr, phenylephrine hcl syrup

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69367-334
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DEXCHLORPHENIRAMINE MALEATE (UNII: B10YD955QW) (DEXCHLORPHENIRAMINE - UNII:3Q9Q0B929N)	DEXCHLORPHENIRAMINE MALEATE	1 mg in 5 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 5 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 5 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics			
Color		**Score**	
Shape		**Size**	
Flavor	COTTON CANDY	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:69367-334-16	480 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/29/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH	part341	07/29/2021	

FINAL	part341	07/29/2021	

Labeler - Westminster Pharmaceuticals, LLC (079516651)

Revised: 8/2021 Westminster Pharmaceuticals, LLC