# DEXTROMETHORPHAN POLISTIREX EXTENDED-RELEASE- dextromethorphan polistirex suspension Amneal Pharmaceuticals LLC

-----

Dextromethorphan Polistirex Extended-Release Suspension 12 Hour Cough Relief Grape

#### **Drug Facts**

#### **OTC - ACTIVE INGREDIENT**

### Active ingredient (in each 5 mL)

Dextromethorphan polistirex equivalent to 30 mg dextromethorphan hydrobromide, USP

#### **OTC - PURPOSE**

#### **Purpose**

Cough suppressant

#### INDICATIONS AND USAGE

#### Uses

Temporarily relieves

- cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants
- the impulse to cough to help you get to sleep

#### WARNINGS

#### Warnings

#### OTC - DO NOT USE

**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.

#### **OTC - ASK DOCTOR**

#### Ask a doctor before use if you have

- chronic cough that lasts such as occurs with smoking, asthma or emphysema
- cough that occurs with too much phlegm (mucus)

**Stop use and ask a doctor if** cough lasts more than 7 days, cough comes back, or occurs with fever, rash or headache that lasts. These could be signs of a serious condition.

#### OTC - PREGNANCY OR BREAST FEEDING

**If pregnant or breast-feeding,** ask a health professional before use.

#### OTC - KEEP OUT OF REACH OF CHILDREN

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

#### **DOSAGE AND ADMINISTRATION**

#### **Directions**

- shake bottle well before use
- measure only with dosing cup provided
- do not use dosing cup with other products
- dose as follows or as directed by a doctor
- mL = milliliter

adults and children 12 years of age and over	10 mL every 12 hours,
	not to exceed 20 mL in 24 hours
children 6 to under 12 years of ago	5 mL every 12 hours,
children o to under 12 years or age	not to exceed 10 mL in 24 hours
children 4 to under 6 years of age	2.5 mL every 12 hours,
children 4 to under 6 years of age	not to exceed 5 mL in 24 hours
children under 4 years of age	do not use

#### Other information

- each 5 mL contains: sodium 7 mg
- store at 20° to 25°C (68° to 77°F)
- dosing cup provided

#### **INACTIVE INGREDIENT**

#### **Inactive ingredients**

citric acid, corn oil, D&C Red No. 33, edetate disodium, ethylcellulose, FD&C Blue No. 1, flavors, methylparaben, polyethylene glycol 3350, polysorbate 80, propylene glycol, propylparaben, purified water, sodium polystyrene sulfonate, sucrose, tragacanth, xanthan gum

Hydrochloric acid or sodium hydroxide solution, if required, to adjust the pH.

# **OTC - QUESTIONS**

#### Questions?

Call 1-877-835-5472, Mon through Fri 9AM to 5PM EST.

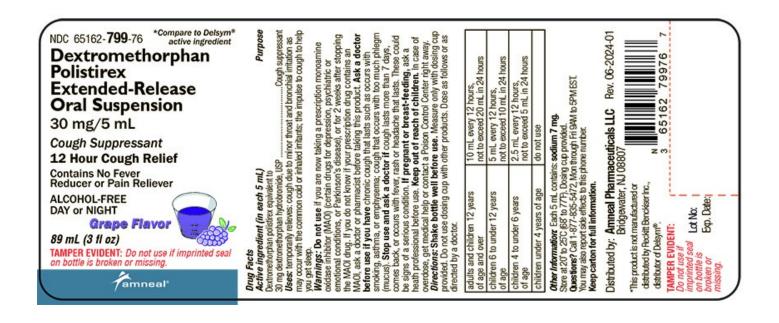
Distributed by:

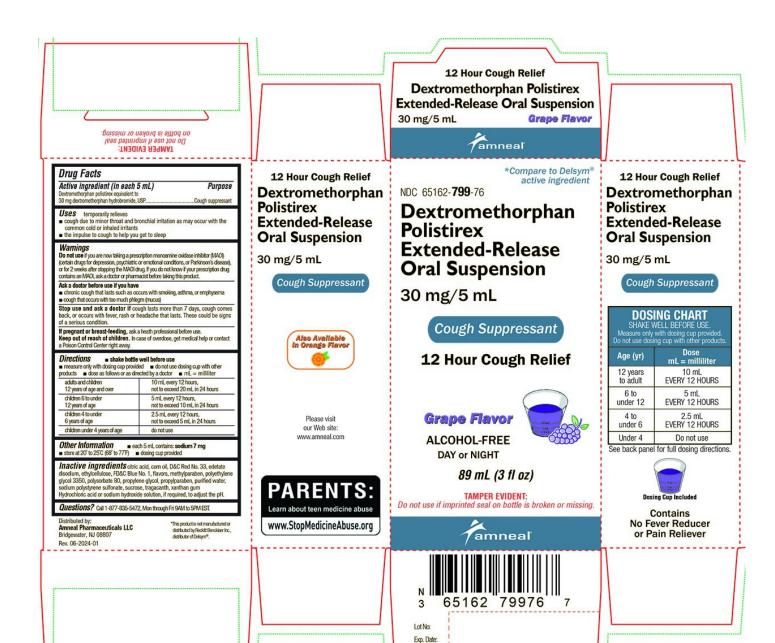
# **Amneal Pharmaceuticals LLC**

Bridgewater, NJ 08807

Rev. 06-2024-01

#### PACKAGE LABEL.PRINCIPAL DISPLAY PANEL





# **DEXTROMETHORPHAN POLISTIREX EXTENDED-RELEASE**

dextromethorphan polistirex suspension

# Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:65162-799 Route of Administration ORAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 5 mL	

#### **Inactive Ingredients**

Ingredient Name	Strength
SODIUM POLYSTYRENE SULFONATE (UNII: 1699G8679Z)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
CORN OIL (UNII: 8470G57WFM)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ETHYLCELLULOSES (UNII: 7Z8S9VYZ4B)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
POLYSORBATE 80 (UNII: 60ZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC10H)	
WATER (UNII: 059QF0KO0R)	
SUCROSE (UNII: C151H8M554)	
TRAGACANTH (UNII: 2944357020)	
XANTHAN GUM (UNII: TTV12P4NEE)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Product Characteristics			
Color	purple	Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65162-799- 76	1 in 1 CARTON	08/01/2017	
1		89 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:65162-799- 77	1 in 1 CARTON	08/01/2017	
2		148 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA203133	08/01/2017	

Establishment			
Name	Address	ID/FEI	Business Operations
Amneal Pharmaceuticals, LLC		963900878	analysis(65162-799), label(65162-799), manufacture(65162-799), pack(65162-799)

Revised: 6/2024 Amneal Pharmaceuticals LLC