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 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

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 age	5 mL every 12 hours, not to exceed 10 mL in 24 hours
children 4 to under 6 years of age	2.5 mL every 12 hours, 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
- mL = milliliter

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

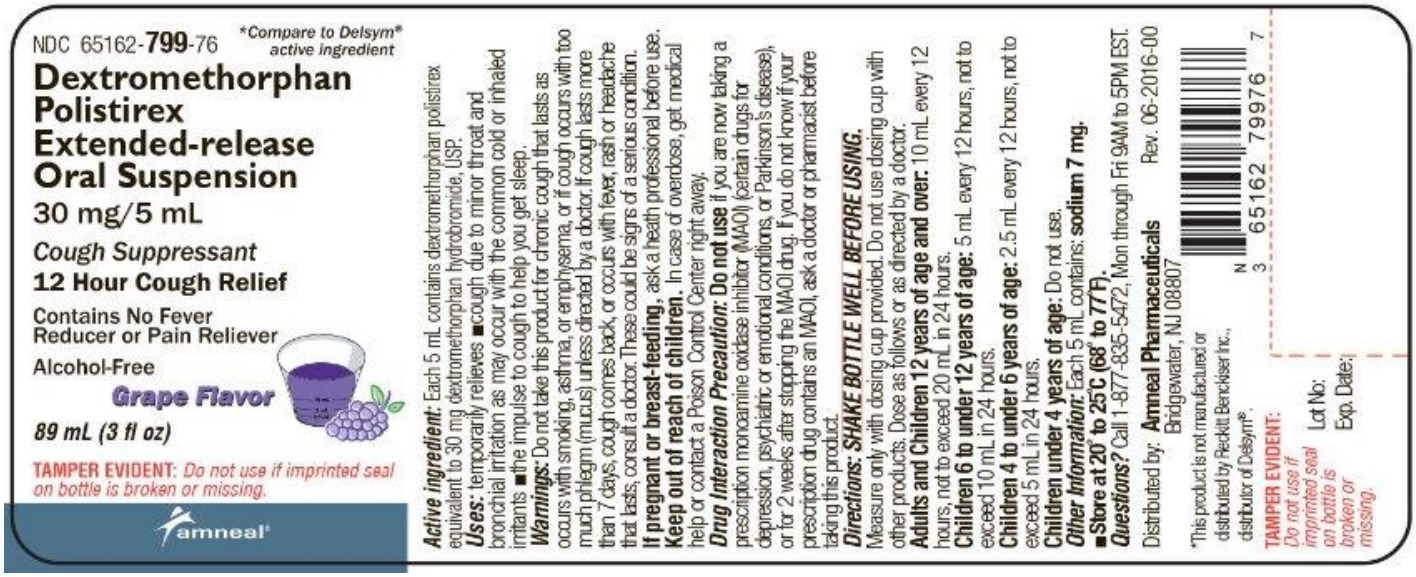
Questions?

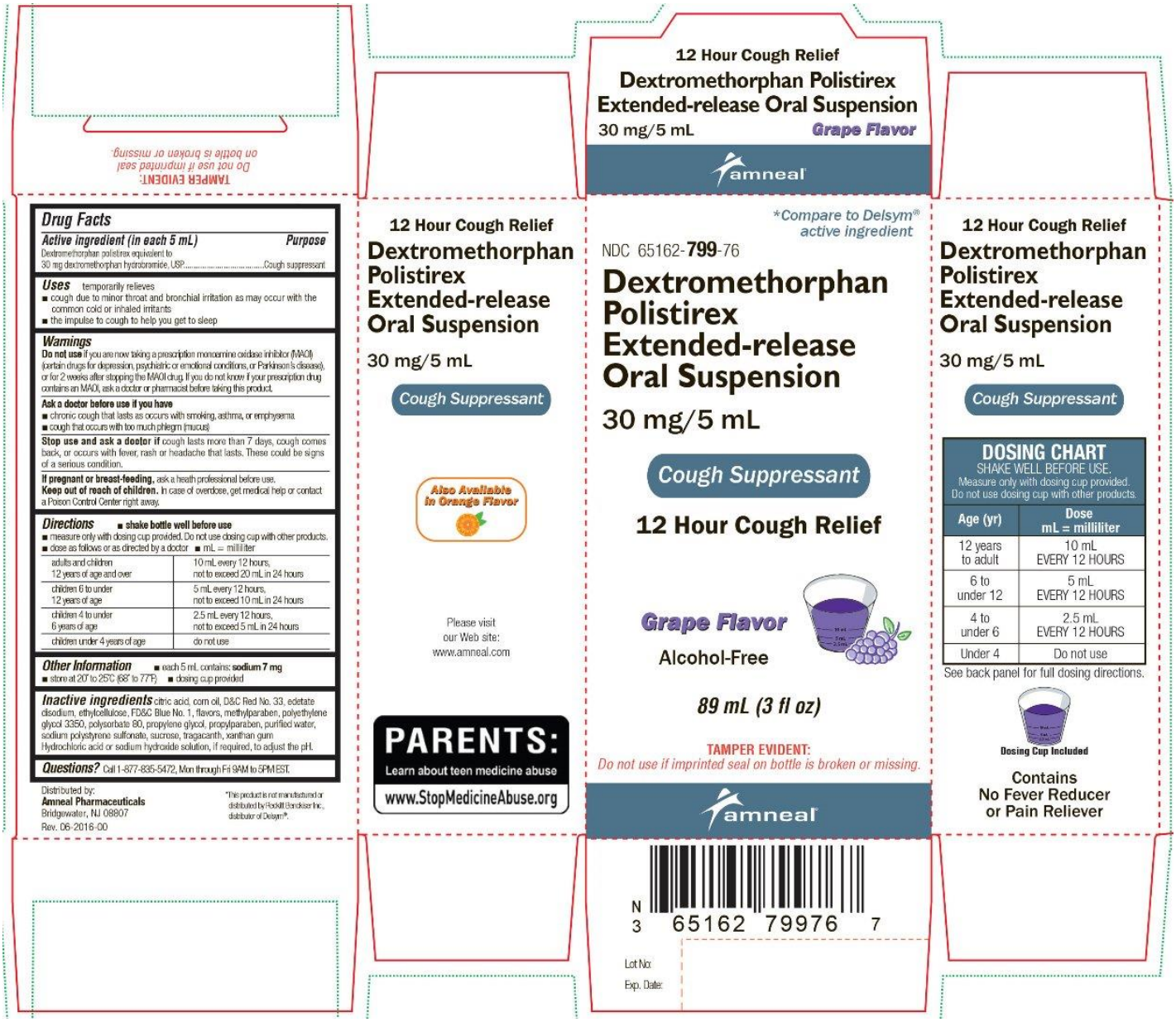
Call 1-877-835-5472, Mon through Fri 9AM to 5PM EST.

Distributed by:
Amneal Pharmaceuticals
Bridgewater, NJ 08807

Rev. 06-2016-00

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**
DEXTROMETHORPHAN HYDROBROMIDE (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: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SUCROSE (UNII: C151H8M554)	
TRAGACANTH (UNII: 2944357O2O)	
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	

Labeler - Amneal Pharmaceuticals LLC (123797875)

Establishment

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

Revised: 12/2023

Amneal Pharmaceuticals LLC