

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

**Dextromethorphan Polistirex Extended-release Suspension
12 Hour Cough Relief
Orange**

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, edetate disodium, ethylcellulose, FD&C Yellow No. 6, flavor, 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

NDC 65162-700-76 *Compare to Delsym®
active ingredient

**Dextromethorphan
Polistirex
Extended-release
Oral Suspension**

30 mg/5 mL

**Cough Suppressant
12 Hour Cough Relief**

Contains No Fever
Reducer or Pain Reliever

Alcohol-Free

Orange Flavor

89 mL (3 fl oz)

TAMPER EVIDENT: Do not use if imprinted seal
on bottle is broken or missing.



Active ingredient: Each 5 mL contains dextromethorphan polistirex
equivalent to 30 mg dextromethorphan hydrobromide, USP.

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 sleep.

Warnings: Do not take this product for chronic cough that lasts as
occurs with smoking, asthma, or emphysema, or if cough occurs with too
much phlegm (mucus) unless directed by a doctor. If cough lasts more
than 7 days, cough comes back, or occurs with fever, rash or headache
that lasts, consult a doctor. These could be signs of a serious condition.
If pregnant or breast-feeding, 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.

Drug Interaction Precaution: 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.

Directions: SHAKE BOTTLE WELL BEFORE USING.
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).

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

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Bridgewater, NJ 08807


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TAMPER EVIDENT:
Do not use if
imprinted seal
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missing.

Lot No: _____
Exp. Date: _____

*This product is not manufactured or
distributed by Perritt-Bendick Inc.,
distributor of Delsym®.

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
CORN OIL (UNII: 8470G57WFM)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ETHYLCELLULOSES (UNII: 7Z8S9VYZ4B)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
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)	
SODIUM POLYSTYRENE SULFONATE (UNII: 1699G8679Z)	

Product Characteristics

Color	orange	Score	
Shape		Size	
Flavor	ORANGE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65162-700-76	1 in 1 CARTON	08/01/2017	
1		89 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:65162-700-77	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(65162-700) , label(65162-700) , manufacture(65162-700) , pack(65162-700)

Revised: 12/2023

Amneal Pharmaceuticals LLC