

**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

NDC 65162-799-76 *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
Grape 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.

Distributed by: **Amneal Pharmaceuticals** Rev. 06-2016-00
Bridgewater, NJ 08807

*This product is not manufactured or distributed by Reckitt Benckiser Inc., distributor of Delsym®.

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

Lot No: _____
Exp. Date: _____


N 3 65162 79976 7

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

Drug Facts

Active ingredient (in each 5 mL)
Dextromethorphan polistirex equivalent to 30 mg dextromethorphan hydrobromide, USP.....Cough suppressant

Purpose

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

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

- 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.

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.

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 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

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 polyethylene sulfonate, sucrose, triacetin, xanthan gum

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

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

Distributed by:
Amneal Pharmaceuticals
Bridgewater, NJ 08807
Rev. 06/2018/00

*This product is not manufactured or distributed by Rodall Chemicals Inc., distributor of Delsym®.

12 Hour Cough Relief
Dextromethorphan Polistirex Extended-release Oral Suspension
30 mg/5 mL

Cough Suppressant

Also Available in Orange Flavor

Please visit our Web site:
www.amneal.com

PARENTS:
Learn about teen medicine abuse
www.StopMedicineAbuse.org

12 Hour Cough Relief
Dextromethorphan Polistirex Extended-release Oral Suspension
30 mg/5 mL

Cough Suppressant

Grape Flavor

Alcohol-Free

89 mL (3 fl oz)

TAMPER EVIDENT:
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amneal



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Lot No:
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Cough Suppressant

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Cough Suppressant

12 Hour Cough Relief
Dextromethorphan Polistirex Extended-release Oral Suspension
30 mg/5 mL

Cough Suppressant

DOSING CHART
SHAKE WELL BEFORE USE.
Measure only with dosing cup provided.
Do not use dosing cup with other products.

Age (yr)	Dose mL = milliliter
12 years to adult	10 mL EVERY 12 HOURS
6 to under 12	5 mL EVERY 12 HOURS
4 to under 6	2.5 mL EVERY 12 HOURS
Under 4	Do not use

See back panel for full dosing directions.


Dosing Cup Included

Contains No Fever Reducer or Pain Reliever

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