

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 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 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 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 LLC

Bridgewater, NJ 08807

Rev. 06-2024-01

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
DAY or NIGHT**

Orange Flavor



89 mL (3 fl oz)
TAMPER EVIDENT: Do not use if imprinted seal on bottle is broken or missing.

amneal

Purpose
Dextromethorphan polistirex equivalent to 30 mg dextromethorphan hydrobromide, USPCough suppressant
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.

Drug Facts
Active ingredient (in each 5 mL)
Dextromethorphan polistirex equivalent to 30 mg dextromethorphan hydrobromide, USP

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 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, 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.

adults and children 12 years of age and over	10 mL every 12 hours; not to exceed 20 mL in 24 hours
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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.

Questions? Call 1-877-835-5472, Mon through Fri 9AM to 5PM EST. You may also report side effects to this phone number.


Keep carton for full information.

Distributed by: **Amneal Pharmaceuticals LLC** Rev. 06-2024-01
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 70076 3

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

Drug Facts

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

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 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.

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
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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, 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.

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

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

Cough Suppressant



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 **Orange Flavor**



*Compare to Delsym® active ingredient

NDC 65162-700-76

Dextromethorphan Polistirex Extended-Release Oral Suspension
 30 mg/5 mL

Cough Suppressant

12 Hour Cough Relief

Orange Flavor

ALCOHOL-FREE DAY or NIGHT

89 mL (3 fl oz)

TAMPER EVIDENT:
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Lot No:
 Exp. Date:

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:65162-700
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
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: 6/2024

Amneal Pharmaceuticals LLC