

**DEXTROMETHORPHAN POLISTIREX - dextromethorphan polistirex suspension, extended release**  
**Aurohealth LLC**

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***Drug Facts***

***Active ingredient (in each 5 mL)***

Dextromethorphan polistirex equivalent to 30 mg dextromethorphan hydrobromide USP

***Purpose***

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, 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 (1-800-222-1222) 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 5 mg**
- store at 20° to 25°C (68° to 77°F)
- dosing cup provided

### ***Inactive ingredients***

citric acid anhydrous, D&C Red no.33, edetate disodium, ethylcellulose, FD & C Blue no. 1, FD & C Red no. 40, grape flavour, high fructose corn syrup, methylparaben, polyethylene glycol, polysorbate 80, propylene glycol, purified water, sucrose, tragacanth, xanthan gum

### ***Questions or comments?***

call **1-855-274-4122** (Monday – Friday 8:30 AM to 5:00 PM EST)

Distributed by:

**AUROHEALTH LLC**

279 Princeton-Hightstown Road  
East Windsor, NJ 08520

Made in India

Code: AP/DRUGS/04/2016

**PRINCIPAL DISPLAY PANEL - 89 mL (3 fl oz) Bottle Label**

**AUROHEALTH**

**NDC 58602-618-05**



P 1438450

**Drug Facts (continued)**

drugs for depression, psychiatric conditions, or Parkinson's disease weeks after stopping the MAOI do not know if your prescription drug MAOI, ask a doctor or pharmacist this product. **Ask a doctor before** have chronic cough that lasts with smoking, asthma, or emphysema that occurs with too much pit cough that occurs with too much pit **Stop use and ask a doctor if** you cough that occurs with too much pit than 7 days, comes back, or occurs rash, or headache that lasts. The signs of a serious condition.

**If pregnant or breast-feeding**, as professional before use. **Keep out of children's reach.** In case of overdose, get help or contact a Poison Control Center at (1-800-222-1222) right away.

**Directions:**

**Shake bottle well before use.** Measure with dosing cup provided. Do not use with other products. Dose as directed by a doctor.

adults and children 12 years of age and over	10 mL every 12 hours
children 6 to under 12 years of age	5 mL every 12 hours
children 4 to under 6 years of age	2.5 mL every 12 hours
children under 4 years of age	do not use

**Other information:** Each 5 mL contains 5 mg. Store at 20° to 25°C (68° to 77°F). See USP Controlled Room Temperature. Excipients include: Dosing cup provided.

Gluing Area

**Base Layer**

Gluing Area

**Drug Facts (continued)**

**Inactive ingredients**

citric acid anhydrous, D&C Red no.33, edetate disodium, ethylcellulose, FD & C Blue no. 1, FD & C Red no. 40, grape flavour, high fructose corn syrup, methylparaben, polyethylene glycol, poly sorbate 80, propylene glycol, purified water, sucrose, tragacanth, xanthan gum

**Questions or comments?** call 1-855-274-4122 (Monday – Friday 8:30 AM to 5:00 PM EST) You may also report side effects to this phone number.

**Keep carton for full information.**

P1438450

**PRINCIPAL DISPLAY PANEL - 89 mL (3 fl oz) Bottle Carton Label**

**AUROHEALTH**

**NDC 58602-618-05**

Compare to Delsym® active ingredient\*

**Dextromethorphan Polistirex Extended-Release Oral Suspension 30 mg/5 mL [Cough Suppressant]**

**COUGH**

**12 HOUR RELIEF**

**grape Flavored Liquid**

**DAY or NIGHT  
ALCOHOL FREE**

**89 mL (3 fl oz)**



**DEXTROMETHORPHAN POLISTIREX**  
dextromethorphan polistirex suspension, extended release

**Product Information**

**Drug Facts (continued)**  
**Other information**  
 ■ each 5 mL contains: sodium 5 mg  
 ■ store at 20° to 25°C (68° to 77°F)  
 ■ dosing cup provided  
**Inactive Ingredients**  
 citric acid anhydrous, D&C Red no.33, edetate disodium, ethylcellulose, FD & C Blue no. 1, FD & C Red no. 40, grape flavour, high fructose corn syrup, methylparaben, polyethylene glycol, polysorbate 80, propylene glycol, purified water, sucrose, tragacanth, xanthan gum  
**Questions or comments?** call 1-855-274-4122 (Monday – Friday 8:30 AM to 5:00 PM EST)

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

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 279 Princeton-Hightstown Road  
 East Windsor, NJ 08520

Made in India

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ALSO AVAILABLE  
 IN ORANGE FLAVOR

**PARENTS:**  
 Learn about teen medicine abuse  
[www.StopMedicineAbuse.org](http://www.StopMedicineAbuse.org)

AUROHEALTH  
 NDC 58602-618-05  
 Compare to Delsym® active ingredient\*

**Dextromethorphan Polistirex Extended-Release Oral Suspension 30 mg/5 mL (Cough Suppressant)**

**COUGH**



grape  
 Flavored Liquid  
**DAY or NIGHT  
 ALCOHOL FREE**  
 89 mL (3 fl oz)

**Dextromethorphan Polistirex Extended-Release Oral Suspension 30 mg/5 mL (Cough Suppressant)**

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

Age (yr)	Dose
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**



Actual Size  
 Contains no Fever Reducer or Pain Reliever

**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, 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 (1-800-222-1222) right away.  
**Directions**  
 ■ shake bottle well before use  
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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



P1063952

\*  
 Unvarnished Zone  
 (dotted line not for printing)  
 47 x 19 mm

Unvarnished Zone  
 (dotted line not for printing)

TAMPER EVIDENT: Do not use if the contents appear different or if the cap is broken or missing.

Unvarnished Zone  
 (dotted line not for printing)

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58602-618
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
<b>POLISTIREX</b> (UNII: 5H9W9GTW27)	
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>D&amp;C RED NO. 33</b> (UNII: 9DBA0SBB0L)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>ETHYLCELLULOSE AQUEOUS DISPERSION TYPE B</b> (UNII: HZJ2V81RYU)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GRAPE</b> (UNII: 6X543N684K)	
<b>HIGH FRUCTOSE CORN SYRUP</b> (UNII: XY6UN3QB6S)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>POLYETHYLENE GLYCOL 6000</b> (UNII: 30IQX730WE)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SUCROSE</b> (UNII: C151H8M554)	
<b>TRAGACANTH</b> (UNII: 2944357O2O)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

### Product Characteristics

<b>Color</b>	PURPLE (Purple to dark purple)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	GRAPE	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-618-05	1 in 1 CARTON	04/17/2026	
1		89 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		
2	NDC:58602-618-06	1 in 1 CARTON	04/17/2026	
2		148 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA218417	04/17/2026	

**Labeler** - Aurohealth LLC (078728447)

## Establishment

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650918514	ANALYSIS(58602-618) , MANUFACTURE(58602-618)

Revised: 4/2026

Aurohealth LLC