

DEXTROMETHORPHAN POLISTIREX - dextromethorphan polistirex suspension, extended release
Aurohealth LLC

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, edetate disodium, ethylcellulose, FD & C Yellow no. 6, high fructose corn syrup, masker citrus flavour, 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 58602-610-05

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

COUGH

AGES 4+

12 HOUR
RELIEF


Contains
no Fever Reducer
or Pain Reliever

orange
Flavored Liquid
For Children & Adults

DAY or NIGHT
ALCOHOL FREE

89 mL (3 fl oz)

Top Layer Printing side




NDC 58602-610-05

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COUGH

AGES 4+



orange
Flavored Liquid
For Children & Adults



Contains
no Fever Reducer
or Pain Reliever

DAY or NIGHT
ALCOHOL FREE
89 mL (3 fl oz)

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

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

PEEL OPEN HERE TO READ COMPLETE WARNINGS AND INFORMATION

Lift Here

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AUROHEALTH LLC
279 Princeton-Hightstown Road
East Windsor, NJ 08520
Made in India
Code: AP/DRUGS/04/2016

P1432439

Position for Vendor logo

* Lot: XXXXXXXXX
EXP: MM/YYYY

Prefix & Variables of Lot, EXP shall be printed online during packing.

Top Layer Adhesive side

P1432439

Drug Facts (continued)

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.

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
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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.

Gluing Area

Base Layer

Gluing Area

(continued)

Ingredients: edetate disodium, C Yellow no. 6, high fructose corn syrup, masker citrus flavour, polyethylene glycol, polysorbate 80, purified water, sucrose, xanthan gum

For more information, call 1-855-274-4122 (10 AM to 5:00 PM EST) You will receive a text message with effects to this phone number.

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

AUROHEALTH

NDC 58602-610-05

Compare to Children's Delsym®
active ingredient*

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

COUGH

**AGES 4+
12 HOUR
RELIEF**

**orange
Flavored Liquid
For Children & Adults**

**DAY or NIGHT
ALCOHOL FREE**

89 mL (3 fl oz)



DEXTROMETHORPHAN POLISTIREX

dextromethorphan polistirex suspension, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58602-610
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
POLISTIREX (UNII: 5H9W9GTW27)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ETHYLCELLULOSE AQUEOUS DISPERSION TYPE B (UNII: HZJ2V81RYU)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SUCROSE (UNII: C151H8M554)	
TRAGACANTH (UNII: 2944357O2O)	
XANTHAN GUM (UNII: TTV12P4NEE)	

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:58602-610-05	1 in 1 CARTON	04/15/2026	
1		89 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		
2	NDC:58602-610-06	1 in 1 CARTON	04/15/2026	
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	04/15/2026	

Labeler - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650918514	ANALYSIS(58602-610) , MANUFACTURE(58602-610)

