

**LEADER CHILDRENS COUGH DM- dextromethorphan polistirex suspension**  
Praxis, LLC

-----  
**Leader Cardinal Health Children's Cough DM Drug Facts**

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

Dextromethorphan polistirex equivalent to 30 mg dextromethorphan hydrobromide

**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.

**Allergy Alert:** Contains sodium metabisulfite, a sulfite that may cause allergic-type reactions.

**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**

- side effects occur. You may report side effects to FDA at 1-800-FDA-1088.
- 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 (1-

800-222-1222).

### 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 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 5 mg
- store at 20° to 25°C (68° to 77°F)
- dosing cup provided

### Inactive Ingredients

D&C Red #30 aluminum lake, D&C Yellow #10 aluminum lake, glycerin, high fructose corn syrup, methylparaben, natural and artificial orange flavor, polysorbate 80, polyvinyl acetate, povidone, propylparaben, purified water, sodium metabisulfite, sodium polystyrene sulfonate, sucrose, tartaric acid, tragacanth gum, triacetin, xanthan gum

### Questions or comments?

**1-800-719-9260**

### Package/Label Principal Display Panel

Children's

Cough DM

Dextromethorphan Polistirex Extended-Release Oral Suspension

Cough Suppressant

Day or Night

For Children & Adults

Orange Flavored Liquid

COMPARE TO CHILDREN'S DELSYM® active ingredient

Age 4+

12 Hour Cough Relief

Dosing Cup Included

Alcohol-Free

Contains No Fever Reducer or Pain Reliever

100% Money Back Guarantee

Contains Sodium Metabisulfite, a Sulfite That May Cause Allergic-Type Reactions

3 FL OZ (89 mL)



**Drug Facts**

**Active ingredient (in each 5 mL)** Purpose  
Dextromethorphan polistirex equivalent to 30 mg dextromethorphan hydrobromide.....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.  
**Allergy Alert:** Contains sodium metabisulfite, a sulfite that may cause allergic-type reactions.

**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**  

- side effects occur. You may report side effects to FDA at 1-800-FDA-1088.
- 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 (1-800-222-1222).

**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 5 mg
- store at 20° to 25°C (68° to 77°F)
- dosing cup provided



**Drug Facts (continued)**

**Inactive ingredients** D&C Red #30 aluminum lake, D&C Yellow #10 aluminum lake, glycerin, high fructose corn syrup, methylparaben, natural and artificial orange flavor, polysorbate 80, polyvinyl acetate, povidone, propylparaben, purified water, sodium metabisulfite, sodium polystyrene sulfonate, sucrose, tartaric acid, tragacanth gum, triacetin, xanthan gum

**Questions or comments?**  
1-800-719-9280

\*This product is not manufactured or distributed by Reckitt Benckiser, distributor of Children's Delsym®. DO NOT USE IF CARTON IS OPENED OR PRINTED FOIL UNDER CAP IS BROKEN OR MISSING

**DOSEING**  
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

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

**LEADER?**

**Children's Cough DM**  
Dextromethorphan Polistirex Extended-Release Oral Suspension Cough Suppressant

**LEADER?**

NDC 70000-0195-1

**Children's Cough DM**  
Dextromethorphan Polistirex Extended-Release Oral Suspension Cough Suppressant Day or Night For Children & Adults

**Orange Flavored Liquid**

Age 4+  
12 Hour Cough Relief  
Dosing Cup Included  
Alcohol-Free  
Contains No Fever Reducer or Pain Reliever

**COMPARE TO CHILDREN'S DELSYM® active ingredient\***

100% Money Back Guarantee

**3 FL OZ (89 mL)**

Contains Sodium Metabisulfite, a Sulfite That May Cause Allergic-Type Reactions

100% Money Back Guarantee

Actual Size



NDC 70000-0195-1  
**Children's Cough DM**  
Dextromethorphan Polistirex Extended-Release Oral Suspension Cough Suppressant Day or Night For Children & Adults

**Orange Flavored Liquid**

Age 4+  
12 Hour Cough Relief  
Dosing Cup Included  
Alcohol-Free  
Contains No Fever Reducer or Pain Reliever

**3 FL OZ (89 mL)**

100% Money Back Guarantee



CIN 5297874 REV. 6/20

0 96295 13046 1

Dist. by CAH, Dublin, OH 43007 1-800-200-6333  
**100% Money Back Guarantee**  
 Return to place of purchase if not satisfied.  
 ©2020 Cardinal Health. CARDINAL HEALTH, the Cardinal Health LOGO, LEADER, and the Leader LOGO are trademarks or registered trademarks of Cardinal Health. All other marks are the property of their respective owners.

COIDE AVRIA

95821 E9 C3

# LEADER CHILDRENS COUGH DM

dextromethorphan polistirex suspension

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59368-249
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 5 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>HIGH FRUCTOSE CORN SYRUP</b> (UNII: XY6UN3QB6S)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM METABISULFITE</b> (UNII: 4VON5FNS3C)	
<b>SODIUM POLYSTYRENE SULFONATE</b> (UNII: 1699G8679Z)	
<b>SUCROSE</b> (UNII: C151H8M554)	
<b>TARTARIC ACID</b> (UNII: W4888I119H)	
<b>TRAGACANTH</b> (UNII: 2944357O2O)	
<b>TRIACETIN</b> (UNII: XHX3C3X673)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	
<b>D&amp;C RED NO. 30</b> (UNII: 2S42T2808B)	
<b>POLYVINYL ACETATE</b> (UNII: 32K497ZK2U)	

## Product Characteristics

<b>Color</b>	orange	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	ORANGE	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59368-249-01	1 in 1 CARTON	11/15/2016	
1		89 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	ANDA091135	11/15/2016	

**Labeler** - Praxis, LLC (016329513)

## Establishment

Name	Address	ID/FEI	Business Operations
Praxis, LLC		016329513	manufacture(59368-249) , label(59368-249) , pack(59368-249)

Revised: 1/2023

Praxis, LLC