

**MEIJER COUGH DM- dextromethorphan polistirex suspension**  
**Praxis, LLC**

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**Meijer Distribution, Inc. 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
- 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

D&C Red #30 aluminum lake, D&C Yellow #10 aluminum lake, flavor, glycerin, high fructose corn syrup, methylparaben, 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

Compare to Children's Delsym® active ingredient

CHILDREN'S cough DM

Dextromethorphan Polistirex

Extended-Release Oral Suspension

Cough Suppressant

AGE 4+

12 HOUR Cough Relief

Orange-Flavored Liquid

Day or Night | Alcohol Free For Children & Adults

Dosing Cup Included

Contains sodium metabisulfite, a sulfite that may cause allergic-type reactions

5 FL OZ (148 mL)

**meijer** Compare to Children's Delsym\* active ingredient\*  
NDC 41250-959-28

**CHILDREN'S cough DM**  
Dextromethorphan Polistirex Extended-Release Oral Suspension Cough Suppressant

**AGE 4+ 12 HOUR Cough Relief**  
Orange-Flavored Liquid

Day or Night | Alcohol Free For Children & Adults

5 FL OZ (148 mL)

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**meijer** NDC 41250-959-28

**CHILDREN'S cough DM**  
Dextromethorphan Polistirex Extended-Release Oral Suspension Cough Suppressant

**AGE 4+ 12 HOUR Cough Relief**  
Orange-Flavored Liquid

Day or Night | Alcohol Free For Children & Adults | Dosing Cup Included  
Contains No Fever Reducer or Pain Reliever

5 FL OZ (148 mL)

actual size  
Also Available in Grape Flavor

**12 HOUR Cough Relief**  
Dextromethorphan Polistirex Extended-Release Oral Suspension | Cough Suppressant

**CHILDREN'S cough DM**

**Drug Facts**

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**Uses** temporarily relieves  
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Stop use and ask a doctor if  
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**Questions or comments?** 1-800-719-9260

\*This product is not manufactured or distributed by Reckitt Benckiser LLC, owner of the registered trademark Delsym®.

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

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)

DIST. BY MEIJER DISTRIBUTION, INC.  
GRAND RAPIDS, MI 49544  
[www.meijer.com](http://www.meijer.com)

**GLUTEN FREE**

**TAMPER EVIDENT:**  
Do not use if carton is opened or neckband imprinted with "sealed for your protection" is broken or missing.

PID 3269528

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LOT NO.  
EXP.  
1 95828 LE C3

**MEIJER COUGH DM**  
dextromethorphan polistirex suspension

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59368-254
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RT19KYH) (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</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:59368-254-02	1 in 1 CARTON	07/08/2013	09/01/2015
1		89 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:59368-254-01	1 in 1 CARTON	07/31/2013	
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	ANDA091135	07/08/2013	

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

## Establishment

Name	Address	ID/FEI	Business Operations
Praxis, LLC		016329513	manufacture(59368-254) , label(59368-254) , pack(59368-254)

Revised: 1/2023

Praxis, LLC