

## **COUGH DM CHILDRENS- dextromethorphan polistirex suspension**

**Meijer Distribution Inc**

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### **Meijer Distribution, Inc. 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 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

D&C Red #30 aluminum lake, FD&C Blue #1, 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?

call **1-800-719-9260**

You may also report side effects to this phone number.

## 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

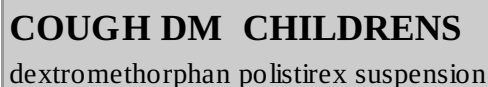
Grape-Flavored Liquid

Day or Night | Alcohol Free

For Children & Adults

Dosing Cup Included

5 FL OZ (148 mL)



## 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	
D&C RED NO. 30 (UNII: 2S42T2808B)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
GLYCERIN (UNII: PDC6A3C0OX)				
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)				
METHYLPARABEN (UNII: A2I8C7HI9T)				
POLYSORBATE 80 (UNII: 6OZP39ZG8H)				
POLYVINYL ACETATE (UNII: 32K497ZK2U)				
POVIDONE (UNII: FZ989GH94E)				
PROPYLPARABEN (UNII: Z8IX2SC1OH)				
WATER (UNII: 059QF0KO0R)				
SODIUM METABISULFITE (UNII: 4VON5FNS3C)				
SODIUM POLYSTYRENE SULFONATE (UNII: 1699G8679Z)				
SUCROSE (UNII: C151H8M554)				
TARTARIC ACID (UNII: W4888I119H)				
TRAGACANTH (UNII: 2944357O2O)				
TRIACETIN (UNII: XHX3C3X673)				
XANTHAN GUM (UNII: TTV12P4NEE)				
Product Characteristics				
Color	PURPLE	Score		
Shape		Size		
Flavor	GRAPE	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41250-899-28	1 in 1 CARTON	03/25/2015	
1		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		03/25/2015	

**Labeler** - Meijer Distribution Inc (006959555)