

**TOPCARE COUGH DM- dextromethorphan polistirex suspension**  
**Topco Associates LLC**

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**Topco Associates LLC. 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

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

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

**1-888-423-0139**

## Package/Label Principal Display Panel

COMPARE TO CHILDREN'S DELSYM® ACTIVE INGREDIENT

children's Cough DM

DEXTROMETHORPHAN POLISTIREX EXTENDED-RELEASE ORAL SUSPENSION COUGH SUPPRESSANT

Dosing Cup Included

OUR PHARMACISTS RECOMMEND

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

12 HOUR COUGH RELIEF

FOR CHILDREN & ADULTS Age 4+

GRAPE FLAVORED LIQUID

3 FL OZ (89 mL)

ALCOHOL-FREE

Day or Night



TOPCARE COUGH DM			
dextromethorphan polistirex suspension			
<b>Product Information</b>			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-899
Route of Administration	ORAL		
<b>Active Ingredient/Active Moiety</b>			
Ingredient Name	Basis of Strength	Strength	
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9 D2RTI9 KYH) (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: HBR47K3TBD)	
GLYCERIN (UNII: PDC6A3C0OX)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POLYVINYL ACETATE (UNII: 32K497ZK2U)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYL PARABEN (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:36800-899-21	1 in 1 CARTON	07/30/2015	
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	07/30/2015	

**Labeler** - Topco Associates LLC (006935977)