COUGH DM- dextromethorphan polistirex suspension, extended release Kroger Company

Kroger Co. 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	10 mL every 12 hours, not to exceed 20 mL in
age	24 hours
and over	
children 6 to under 12 years of	5 mL every 12 hours, not to exceed 10 mL in
age	24 hours
children 4 to under 6 years of	2.5 mL every 12 hours, not to exceed 5 mL in
age	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?

1-800-632-6900

Package/Label Principal Display Panel

OUR PHARMACIST RECOMMENDED

Cough DM

Dextromethorphan Polistirex Extended-Release Oral Suspension

COUGH SUPPRESSANT

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

Day or Night

Alcohol-Free

Dosing Cup Included

12 HOUR COUGH RELIEF

Grape-Flavored Liquid 3 FL OZ (89 mL) **Dextromethorphan Polistirex** Extended-Release Oral Suspension COUGH SUPPRESSANT

Do not use if carton is opened or printed foil under cap is broken or missing



COMPARE TO the active ingredient of DELSYM® GRAPE-FLAVOR *See side panel

NDC 30142-494-21





Cough DM

Dextromethorphan Polistirex Extended-Release Oral Suspension

COUGH SUPPRESSANT

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

Day or Night Alcohol-Free **Dosing Cup Included**

COUGH RELIEF



Grape-Flavored Liquid 3 FL OZ (89 mL)





NDC 30142-494-21

ough DM

Dextromethorphan Polistirex Extended-Release Oral Suspension

COUGH SUPPRESSANT



Contains No Fever Reducer or Pain Reliever Day or Night Alcohol-Free Dosing Cup Included Grape-Flavored Liquid 3 FL OZ (89 mL)



DISTRIBUTED BY THE KROGER CO. CINCINNATI, OHIO 45202 QUALITY GUARANTEE 800-632-6900 www.kroger.com

GLUTEN FREE

GODE AREA

49421 45 C3



Way Cough DM



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

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- 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	10 mL every 12 hours,	
12 years of age and over	not to exceed 20 mL in 24 hours	
children 6 to under	5 mL every 12 hours,	
12 years of age	not to exceed 10 mL in 24 hours	
children 4 to under	2.5 mL every 12 hours,	
6 years of age	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 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? 1-800-632-6900

DOSING

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

*Delsym[®] is a registered trademark of RB Health (US) LLC, Parsippany, NJ 07054. RB Health (US) LLC is not affiliated with The Kroger Co. or this product.

Also Available in Orange Flavor

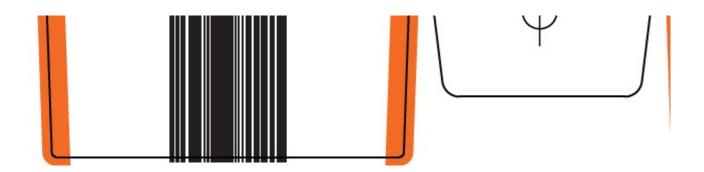
PARENTS

Learn about teen medicine abuse

www.StopMedicineAbuse.org







COUGH DM

dextromethorphan polistirex suspension, extended release

Product I	nformation
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Product TypeHUMAN OTC DRUGItem Code (Source)NDC:30 142-494

Route of Administration ORAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9 D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) DEXTROMETHORPHAN - UNII:7355X3ROTS) DEXTROMETHORPHAN in 5 mL

Inactive Ingredients		
Ingredient Name	Strength	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
GLYCERIN (UNII: PDC6A3C0OX)		
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)		
METHYLPARABEN (UNII: A218 C7HI9 T)		
POLYSORBATE 80 (UNII: 6OZP39ZG8H)		
POLYVINYL ACETATE (UNII: 32K497ZK2U)		
PO VIDO NE, UNSPECIFIED (UNII: FZ989GH94E)		
PROPYLPARABEN (UNII: Z8IX2SC1OH)		
WATER (UNII: 059QF0KO0R)		
SODIUM METABISULFITE (UNII: 4VON5FNS3C)		
SODIUM POLYSTYRENE SULFONATE (UNII: 1699G8679Z)		
SUCROSE (UNII: C151H8 M554)		
TARTARIC ACID (UNII: W4888I119H)		
TRAGACANTH (UNII: 2944357O2O)		
TRIACETIN (UNII: XHX3C3X673)		
XANTHAN GUM (UNII: TTV12P4NEE)		
D&C RED NO. 30 (UNII: 2S42T2808B)		

Product Characteristics			
Color	PURPLE	Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	

Contains

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
NDC:30142-494-21	1 in 1 CARTON	06/28/2018		
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	06/28/2018	

Labeler - Kroger Company (006999528)

Revised: 9/2020 Kroger Company