COUGH DM- dextromethorphan polistirex suspension, extended release
Praxis, LLC

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 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?

1-800-632-6900

Package/Label Principal Display Panel

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

Kroger®

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)

0 41260 38667 1

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

GLUTEN FREE

PLEASE RECYCLE

ACTUAL SIZE


CODE AREA
49421 45 C3

Cough DM

Kroger®

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 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

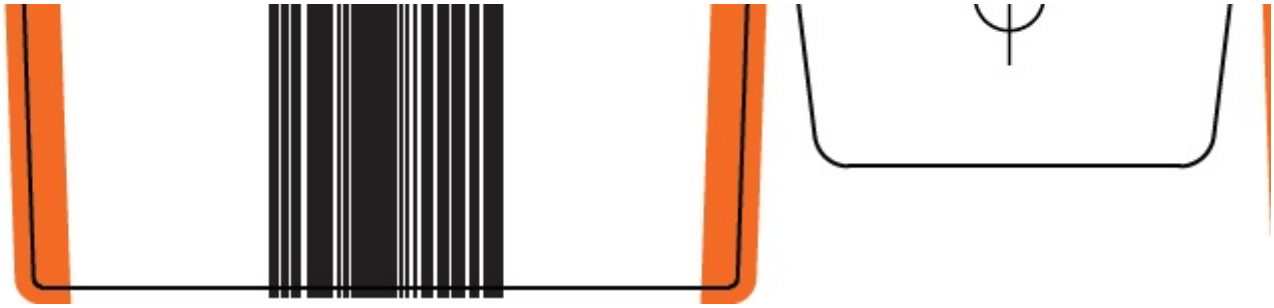
See back panel for full dosing directions.

Dosing cup included

*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 Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:59368-259
Route of Administration	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**
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, UNSPECIFIED (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)	
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
1	NDC:59368-259-01	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 - Praxis, LLC (016329513)

Establishment

Name	Address	ID/FEI	Business Operations
Praxis, LLC		016329513	manufacture(59368-259) , label(59368-259) , pack(59368-259)

Revised: 1/2023 Praxis, LLC