

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

Cardinal Health 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?

1-800-719-9260

Package/Label Principal Display Panel

Day or Night

Cough DM

Dextromethorphan Polistirex Extended-Release Oral Suspension

Cough Suppressant

Grape Flavored Liquid

12 Hour Cough Relief

Alcohol-Free

Dosing Cup Included

COMPARE TO DELSYM® active ingredient

100% Money Back Guarantee

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

3 FL OZ (89 mL)

DO NOT USE IF CARTON IS OPENED OR PRINTED FOIL UNDER CAP IS BROKEN OR MISSING

LEADER²

Day or Night

Cough DM

Dextromethorphan Polistirex
Extended-Release Oral Suspension
Cough Suppressant

LEADER²

NDC 70000-0302-1

Day or Night

Cough DM

Dextromethorphan Polistirex
Extended-Release Oral Suspension
Cough Suppressant



Grape

Flavored Liquid

12 Hour Cough Relief

Alcohol-Free

Dosing Cup Included

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**COMPARE TO
DELSYM[®]**
active ingredient*

100% Money
Back Guarantee

3 FL OZ (89 mL)

DO NOT USE IF CARTON IS OPENED OR PRINTED
FOIL UNDER CAP IS BROKEN OR MISSING

CIN 5332101 REV. 6/20



Dist. by CAH, Dublin, OH 43017 1-800-200-6313

100% Money Back Guarantee
Return to place of purchase if not satisfied.

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LOGO are trademarks or registered trademarks
of Cardinal Health. All other marks are the
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Actual Size



CODE AREA

49421 E9 C3



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Drug Facts (continued)

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*This product is not manufactured or distributed by Reckitt Benckiser, distributor of Delsym®.

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.



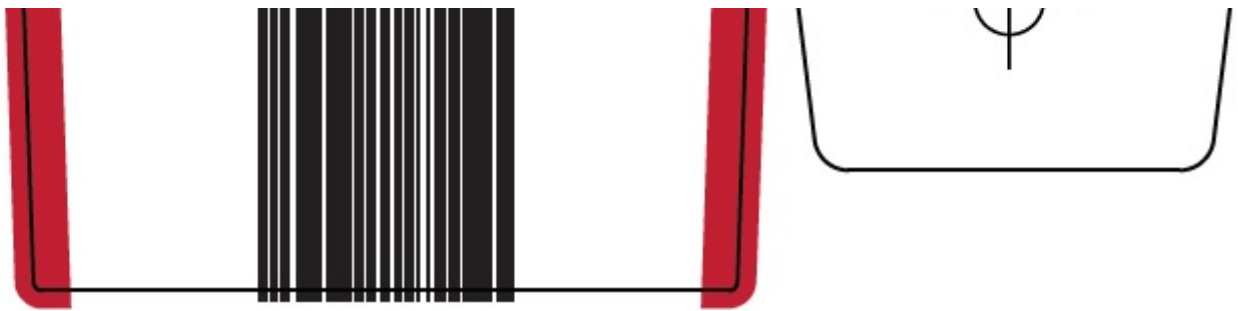
Dosing cup
included

Also
Available in
Orange Flavor

PARENTS:

Learn about teen medicine abuse

www.StopMedicineAbuse.org



LEADER COUGH DM

dextromethorphan polistirex suspension, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59368-258
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:59368-258-01	1 in 1 CARTON	06/06/2017	
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		06/06/2017	

Labeler - Praxis, LLC (016329513)

Establishment

Name	Address	ID/FEI	Business Operations
Praxis, LLC		016329513	manufacture(59368-258) , label(59368-258) , pack(59368-258)

Revised: 1/2023

Praxis, LLC