COUGH DM- dextromethorphan polistirex suspension **Praxis**, **LLC**

Walgreen 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

- 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-

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 doctor

adults and children 12	10 mL every 12 hours, not to
years of age and over	exceed 20 mL in 24 hours
children 6 to under 12	5 mL every 12 hours, not to
years of age	exceed 10 mL in 24 hours
children 4 to under 6 years	2.5 mL every 12 hours, not to
of age	exceed 5 mL in 24 hours
children under 4 years of	do not use
age	

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, D&C Yellow #10 aluminum lake, glycerin, high fructose corn syrup, methylparaben, natural and artificial orange flavor, 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

Walgreens

WALGREENS PHARMACIST RECOMMENDED

Compare to the active ingredient in Delsym ®

12 - HOUR COUGH RELIEF

Cough DM

DEXTROMETHORPHAN POLISTIREX

EXTENDED-RELEASE ORAL SUSPENSION / COUGH SUPPRESSANT

12 Hour

Day Or Night

- Contains sodium metabisulfite, a sulfite that may cause allergic-type reactions
- Alcohol free

Dosing cup included

3 FL OZ (89 mL)

Orange flavored liquid



COUGH DM

dextromethorphan polistirex suspension

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:59368-269

ORAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 5 mL	

Inactive Ingredients		
Ingredient Name	Strength	
POLISTIREX (UNII: 5H9W9GTW27)		
D&C RED NO. 30 (UNII: 2S42T2808B)		
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)		
GLYCERIN (UNII: PDC6A3C0OX)		
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)		
METHYLPARABEN (UNII: A218C7HI9T)		
POLYSORBATE 80 (UNII: 60ZP39ZG8H)		
POLYVINYL ACETATE (UNII: 32K497ZK2U)		
POVIDONE, UNSPECIFIED (UNII: FZ 989GH94E)		
PROPYLPARABEN (UNII: Z8IX2SC10H)		
WATER (UNII: 059QF0KO0R)		
SODIUM METABISULFITE (UNII: 4VON5FNS3C)		
SODIUM POLYSTYRENE SULFONATE (UNII: 1699G8679Z)		
SUCROSE (UNII: C151H8M554)		
TARTARIC ACID (UNII: W4888I119H)		
TRAGACANTH (UNII: 2944357020)		
TRIACETIN (UNII: XHX3C3X673)		
XANTHAN GUM (UNII: TTV12P4NEE)		

Product Characteristics			
Color	orange	Score	
Shape		Size	
Flavor	ORANGE	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59368-269- 01	1 in 1 CARTON	08/28/2012	
1		89 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:59368-269- 02	1 in 1 CARTON	07/16/2013	
2		148 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Application Number or Monograph Category Citation		Marketing Start Date	Marketing End Date
ANDA	ANDA091135	08/28/2012	

Labeler - Praxis, LLC (016329513)

Establishment			
Name	Address	ID/FEI	Business Operations
Praxis, LLC		016329513	manufacture(59368-269) , label(59368-269) , pack(59368-269)

Revised: 1/2023 Praxis, LLC