#### WALGREENS CHILDRENS COUGH DM- dextromethorphan polistirex suspension Praxis, LLC

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# Walgreen Co. Children's 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

Compare to Children's Delsym <sup>®</sup>active ingredient

children's

12 - HOUR COUGH RELIEF

Cough DM

DEXTROMETHORPHAN POLISTIREX EXTENDED-RELEASE ORAL SUSPENSION

COUGH SUPPRESSANT

12 HOUR

ALCOHOL FREE

DAY OR NIGHT

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

For children & adults

AGES 4 & OLDER

**GRAPE-FLAVORED LIQUID** 

3 FL OZ (89 mL)

Dosing cup included



Product Information				
Product Type	HUMAN OTC DRUG	HUMAN OTC DRUG Item Code (Source)		
Route of Administration	ORAL			
Active Ingredient/Activ	ve Moiety			
Ing	redient Name		Basis of Streng	gth Strength
<b>EXTROMETHORPHAN HYDR</b> DEXTROMETHORPHAN - UNII:73	DEXTROMETHORPHAN HYDROBROMIDE	I 30 mg in 5 mL		
nactive Ingredients				
	Ingredient Nar	ne		Strength
&C RED NO. 30 (UNII: 2542T	2808B)			
D&C BLUE NO. 1 (UNII: H3R4	7K3TBD)			
LYCERIN (UNII: PDC6A3C0OX)				
IIGH FRUCTOSE CORN SYRU	P (UNII: XY6UN3QB6S)			
IETHYLPARABEN (UNII: A218C	7HI9T)			
OLYSORBATE 80 (UNII: 60ZI	P39ZG8H)			
OLYVINYL ACETATE (UNII: 32	2K497ZK2U)			
OVIDONE, UNSPECIFIED (UN	NII: FZ989GH94E)			
ROPYLPARABEN (UNII: Z8IX2	SC1OH)			
ATER (UNII: 059QF0KO0R)				
ODIUM METABISULFITE (UN	III: 4VON5FNS3C)			
UCROSE (UNII: C151H8M554)				
ODIUM POLYSTYRENE SULF	ONATE (UNII: 1699G8679	)		
ARTARIC ACID (UNII: W488811	.19H)			
RAGACANTH (UNII: 2944357C	20)			
RIACETIN (UNII: XHX3C3X673)	)			
ANTHAN GUM (UNII: TTV12P4	NEE)			
Product Characteristic	re la			
color	purple	Score		
hape		Size		
lavor	GRAPE	Imprint Code		
contains		imprint Code		
ontains				

#Item CodePackage DescriptionMarketing Start<br/>DateMarketing End<br/>Date1NDC:59368-247<br/>011 in 1 CARTON06/12/201506/12/20151S9 mL in 1 BOTTLE; Type 0: Not a Combination<br/>ProductFor the second se

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
ANDA	ANDA091135	06/12/2015				

Labeler - Praxis, LLC (016329513)

Establishment				
Name	Address	ID/FEI	Business Operations	
Praxis, LLC		016329513	manufacture(59368-247) , label(59368-247) , pack(59368-247)	

Revised: 1/2023

Praxis, LLC