WALGREENS CHILDRENS COUGH DM- dextromethorphan polistirex suspension Praxis, LLC

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 [®]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
EXTROMETHORPHAN HYDR 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
DateMarketing End
Date1NDC:59368-247
011 in 1 CARTON06/12/201506/12/20151S9 mL in 1 BOTTLE; Type 0: Not a Combination
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