GOOD SENSE COUGH DM- dextromethorphan polistirex suspension Praxis, LLC

Perrigo 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-

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 years of age and	10 mL every 12 hours, not to exceed 20
over	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

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

Alcohol-Free

Cough Dm

Dextromethorphan Polistirex Extended-Release Oral Suspension

Cough Suppressant

12 Hour Cough Relief

Orange-Flavored Liquid

Dosing Cup Included

Day or Night

Contains sodium metabisulfite, a sulfite that may cause allergic-type reactions Compare to active ingredient of Delsym $^{\circledR}$

100% SATISFACTION GUARANTEED

5 FL OZ (148 mL)



GOOD SENSE COUGH DM

dextromethorphan polistirex suspension

D	rac	luct	Infor	mation
Г	100	IUCL		IIIatioii

Product Type HUMAN OTC DRUG Item Code (Source) NDC:59368-276

Route of Administration

ORAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH)	DEXTROMETHORPHAN	30 mg

(DEXTROMETHORPHAN - UNII:7355X3ROTS)

DEXTROMETHORPHAN 30 mg HYDROBROMIDE 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: A2I8C7HI9T)	
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			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59368-276- 01	1 in 1 CARTON	07/25/2013	
1		148 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing In	formation		
Marketing	Application Number or Monograph	Marketing Start	Marketing End

Category	Citation	Date	Date
ANDA	ANDA091135	02/01/2013	

Labeler - Praxis, LLC (016329513)

Establishment			
Name	Address	ID/FEI	Business Operations
Praxis, LLC		016329513	manufacture(59368-276) , label(59368-276) , pack(59368-276)

Revised: 1/2023 Praxis, LLC