

SIGNATURE CARE CHILDRENS 12 HOUR COUGH RELIEF- dextromethorphan polistirex suspension
Praxis, LLC

Signature Care Better Living Brands LLC Children's 12 Hour Cough Relief 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

Signature Care[®]

Quality Guaranteed

AGES 4 AND OLDER

Children's 12 Hour Cough Relief

DEXTROMETHORPHAN POLISTIREX

EXTENDED-RELEASE
ORAL SUSPENSION
Cough Suppressant
GRAPE

-FLAVORED LIQUID

Day or Night

For Children & Adults

- Alcohol-free
- Dosing Cup Included

3 FL OZ (89 mL)

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



DISTRIBUTED BY:
BETTER LIVING BRANDS LLC
P.O. BOX 89, PLEASANTON,
CA 94568-0089
1-888-723-3929
www.betterlivingbrandsLLC.com

OUR PROMISE
QUALITY & SATISFACTION
100%
GUARANTEED
OR YOUR MONEY BACK.

Drug Facts

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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

Drug Facts (continued)

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

*This product is not manufactured or distributed by Reckitt Benckiser, distributor of Children's 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.



PARENTS:
 Learn about teen medicine abuse
www.StopMedicineAbuse.org

Do not use if carton is opened or printed foil under cap is broken or missing



Compare to Children's Delsym® active ingredient*
NDC 21130-890-21

Quality Guaranteed

AGES 4 AND OLDER
Children's 12 Hour Cough Relief

DEXTROMETHORPHAN POLISTIREX EXTENDED-RELEASE ORAL SUSPENSION
 Cough Suppressant

GRAPE -FLAVORED LIQUID
 Day or Night
 For Children & Adults
 • Alcohol-free
 • Dosing Cup Included
3 FL OZ (89 mL)

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

ACTUAL SIZE



Signature Care Quality Guaranteed
 NDC 21130-890-21

Children's 12 Hour Cough Relief
 AGE 4+

DEXTROMETHORPHAN POLISTIREX EXTENDED-RELEASE ORAL SUSPENSION
 Cough Suppressant

GRAPE -FLAVORED LIQUID
 Day or Night
 For Children & Adults
 Alcohol-free
 Dosing Cup Included
 Contains No Fever Reducer or Pain Reliever
3 FL OZ (89 mL)

S 1872 RD 21022



Scan here for more information



89921 LJ C1

SIGNATURE CARE CHILDRENS 12 HOUR COUGH RELIEF

dextromethorphan polistirex suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59368-246
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
D&C RED NO. 30 (UNII: 2S42T2808B)	
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)	

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:59368-246-	1 is 1 CARTON	05/27/2022	

1	01	1 IN 1 CARTON	05/27/2022	
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		05/27/2022	

Labeler - Praxis, LLC (016329513)

Establishment			
Name	Address	ID/FEI	Business Operations
Praxis, LLC		016329513	manufacture(59368-246) , label(59368-246) , pack(59368-246)

Revised: 1/2023

Praxis, LLC