SIGNATURE CARE CHILDRENS 12 HOUR COUGH RELIEF- dextromethorphan polistirex suspension Safeway

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	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

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 99, PLEASANTON

OUR PROMISE GUARANTEED

Drug Facts

Active ingredient (in each 5 mL) Purpose Dextromethorphan polistirex equivalent to 30 mg dextromethorphan hydrobromide...

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 (MAD) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MADI drug. If you do not know if your prescription drug contains an MADI, ask a doctor or pharmacist before taking this product.

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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	10 mL every 12 hours,
12 years of age and over	not to exceed 20 mL in 24 hours
children 6 to under	5 mL every 12 hours,
12 years of age	not to exceed 10 mL in 24 hours
children 4 to under	2.5 mL every 12 hours,
6 years of age	not to exceed 5 mL in 24 hours
abildana and an American afterna	do not uso

Other information
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Drug Facts (continued)

Inactive ingredients artificial grape flavor, D&C Red #30 aluminum lake, FD&C flavor, D&C Hed #30 alumnum lake, FUSC Blue #1 alumnum lake, glycerin, high fructos corn syrup, methylparaben, polysorbate 80, polyvinyl acetate, povidone, propylparaben, purified water, sodium metabisulifite, sodium polystyrene sulfonate, sucrose, tartaric cid, 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®

SHAKE WELL BEFORE USE.

Measure only with dosing cup provided.
onot use dosing cup with other products Age (yr) 12 years to adult 10 mL EVERY 12 HOURS 6 to under 12 5 mL EVERY 12 HOURS

Under 4 Do not use See back panel for full dosing directions.

2.5 mL EVERY 12 HOURS





www.StopMedicineAbuse.org

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



AGES 4 AND OLDER

Children's 12 Hour Cough Relief

EXTENDED-RELEASE ORAL SUSPENSION









SIGNATURE CARE CHILDRENS 12 HOUR COUGH RELIEF

dextromethorphan polistirex suspension

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:21130-890

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength

DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH)

(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: 2944357020)	
TRIACETIN (UNII: XHX3C3X673)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics			
Color	PURPLE	Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21130-890- 21	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 - Safeway (009137209)

Revised: 6/2022 Safeway