

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

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**Better Living Brands LLC 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 doctor
- mL = milliliter

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

D&C Red #30 aluminum lake, D&C Yellow #10 aluminum lake, flavor, 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?

**1-888-723-3929**

### Package/Label Principal Display Panel

Compare to Delsym® active ingredient

Quality Guaranteed

12 Hour Cough Relief

DEXTROMETHORPHAN POLISTIREX EXTENDED-RELEASE ORAL SUSPENSION

Cough Suppressant

ORANGE-FLAVORED LIQUID

Day or Night

Alcohol-free

Dosing Cup Included

3 FL OZ (89 mL)

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



## SIGNATURE CARE 12 HOUR COUGH RELIEF

dextromethorphan polistirex suspension

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:21130-012
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 5 mL

### Inactive Ingredients

Ingredient Name	Strength

<b>POLISTIREX</b> (UNII: 5H9W9GTW27)
<b>D&amp;C RED NO. 30</b> (UNII: 2S42T2808B)
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)
<b>HIGH FRUCTOSE CORN SYRUP</b> (UNII: XY6UN3QB6S)
<b>METHYL PARABEN</b> (UNII: A2I8C7HI9T)
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)
<b>POLYVINYL ACETATE</b> (UNII: 32K497ZK2U)
<b>POVIDONE</b> (UNII: FZ989GH94E)
<b>PROPYL PARABEN</b> (UNII: Z8IX2SC1OH)
<b>WATER</b> (UNII: 059QF0KO0R)
<b>SODIUM METABISULFITE</b> (UNII: 4VON5FNS3C)
<b>SODIUM POLYSTYRENE SULFONATE</b> (UNII: 1699G8679Z)
<b>SUCROSE</b> (UNII: C151H8M554)
<b>TARTARIC ACID</b> (UNII: W4888I119H)
<b>TRAGACANTH</b> (UNII: 2944357O2O)
<b>TRIACETIN</b> (UNII: XHX3C3X673)
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)

### Product Characteristics

<b>Color</b>	ORANGE	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	ORANGE	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21130-012-21	1 in 1 CARTON	09/08/2015	
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	09/08/2015	

**Labeler** - Safeway (009137209)