# 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 | 10 mL every 12 hours, not to exceed 20 mL in |
|---------------------------------|--|
| age and over                    | 24 hours                                     |
| children 6 to under 12 years of | 5 mL every 12 hours, not to exceed 10 mL in  |
| age                             | 24 hours                                     |
| children 4 to under 6 years of  | 2.5 mL every 12 hours, not to exceed 5 mL in |
| age                             | 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



TAMPE R EVIDENT: Do not use if carton is open ed or neckband. Imprinted with "sea led for your protection" is broken or missing.

## 100% GUARANTEED

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# 12 Hour Cough Relief

DEXTROMETHORPHAN POLISTIREX EXTENDED-RELEASE ORAL SUSPENSION



Dosing Cup Included



#### **Drug Facts**

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.Cough suppressant

Purpose

Drug Facts (continued)

Questions or comments? 1-898-723-3929

Age (yr)

6 to under 12

Under 4

Drug racks (colimited soc Red #30 alaminum lake, D.RC Vellow #10 alaminum lake (D.RC Vellow #10 alaminum lake (D.RC Vellow), polyporate paratise, polyporate paratise, polyporate paratise date; polyporate propilparates purified water, sodium metablisulfite, sodium polystyrene sudinonate, secroes, tratrice acid, tragacanth gum, triacetia, xanthan gum

\*This product is not manufactured or distributed by Reckitt Benckiser, distributor of Delsym®.

DOSING SHAKE WELL BEFORE USE.

10 mL EVERY 12 HOURS

5 mL EVERY 12 HOURS

2.5 mL EVERY 12 HOURS

Do not use See back panel for full dosing directions

Dosing cup included

www.StopMedicineAbuse.org

- 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
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   do not use dosing cup with other products
   dose as follows or as directed by doctor
   ml = millifer

| 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  |

■ each 5 mL contains: sodium 5 mg ■ dosing cup provided

Other information
store at 20° to 25°C (68° to 77°F)

LOT NO.

EXP.

: 38457 F1 CS

## SIGNATURE CARE 12 HOUR COUGH RELIEF

dextromethorphan polistirex suspension

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:21130-012

**Route of Administration** ORAL

#### **Active Ingredient/Active Moiety**

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

#### **Inactive Ingredients**

**Ingredient Name** 

Strength

| POLISTIREX (UNII: 5H9 W9 GTW27)                 |  |
|---|--|
| <b>D&amp;C RED NO. 30</b> (UNII: 2S42T2808B)    |  |
| D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)            |  |
| GLYCERIN (UNII: PDC6A3C0OX)                     |  |
| HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)     |  |
| METHYLPARABEN (UNII: A218 C7H19 T)              |  |
| POLYSORBATE 80 (UNII: 6OZP39ZG8H)               |  |
| POLYVINYL ACETATE (UNII: 32K497ZK2U)            |  |
| PO VIDO NE (UNII: FZ989 GH94E)                  |  |
| PROPYLPARABEN (UNII: Z8IX2SC1OH)                |  |
| WATER (UNII: 059QF0KO0R)                        |  |
| SODIUM METABISULFITE (UNII: 4VON5FNS3C)         |  |
| SODIUM POLYSTYRENE SULFONATE (UNII: 1699G8679Z) |  |
| SUCROSE (UNII: C151H8 M554)                     |  |
| TARTARIC ACID (UNII: W4888I119H)                |  |
| TRAGACANTH (UNII: 2944357O2O)                   |  |
| TRIACETIN (UNII: XHX3C3X673)                    |  |
| XANTHAN GUM (UNII: TTV12P4NEE)                  |  |

| Product Characteristics |        |              |  |
|-------------------------|--------|--------------|--|
| Color                   | ORANGE | Score        |  |
| Shape                   |        | Size         |  |
| Flavor                  | ORANGE | Imprint Code |  |
| Contains                |        |              |  |

| Packaging          |  |                             |                           |
|--------------------|--|-----------------------------|---------------------------|
| # Item Code        | Package Description                                  | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
| 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)

Revised: 2/2019 Safeway