

## **12 HOUR COUGH RELIEF- dextromethorphan polistirex suspension**

**Western Family Foods Inc**

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### **Western Family 12 Hour Cough Relief Drug Facts**

#### **Active ingredient (in each 5 mL)**

Dextromethorphan polistirex equivalent to 30 mg dextromethorphan hydrobromide, USP

#### **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?

1-800-719-9260

### Package/Label Principal Display Panel

12 HOUR COUGH RELIEF

DEXTROMETHORPHAN POLISTIREX EXTENDED-RELEASE ORAL SUSPENSION

Cough Suppressant

Dosing Cup Included

Alcohol-free

Orange-Flavored Liquid

COMPARE TO ACTIVE INGREDIENT IN DELSYM®

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

3 FL OZ (89 mL)



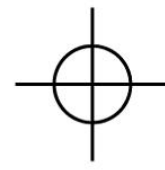
**12 HOUR  
COUGH RELIEF**



**Orange-Flavored  
Liquid**

**TAMPER EVIDENT:**

Do not use if carton is opened or neckband imprinted with "sealed for your protection" is broken or missing.



**12 HOUR  
COUGH RELIEF**

DEXTROMETHORPHAN POLISTIREX  
EXTENDED-RELEASE ORAL SUSPENSION  
**Cough Suppressant**

Dosing Cup  
Included

Alcohol-free

**Orange-Flavored Liquid**



**COMPARE TO ACTIVE INGREDIENT IN DELSYM®\***

**3 FL OZ (89 mL)**

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

ACTUAL SIZE



**12 HOUR  
COUGH RELIEF**

DEXTROMETHORPHAN POLISTIREX  
EXTENDED-RELEASE ORAL SUSPENSION  
**Cough Suppressant**

Contains no fever reducer or pain reliever

Alcohol-free  
**Orange-Flavored Liquid**

**3 FL OZ (89 mL)**



Dosing Cup Included

2959-A-PER



Proudly Distributed by  
Western Family Foods, Inc

12



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[www.westernfamily.com](http://www.westernfamily.com)

LOT NO.

**CODE AREA**

EXP.

: 38421 3W C1







## Drug Facts

### Active ingredient (in each 5 mL)

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### Purpose

### 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

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## Drug Facts (continued)

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### Questions or comments?

1-800-719-9260

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

## DOSING

SHAKE WELL BEFORE USE.

Measure only with dosing cup provided. Do not use dosing cup with other products. mL = milliliter

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.



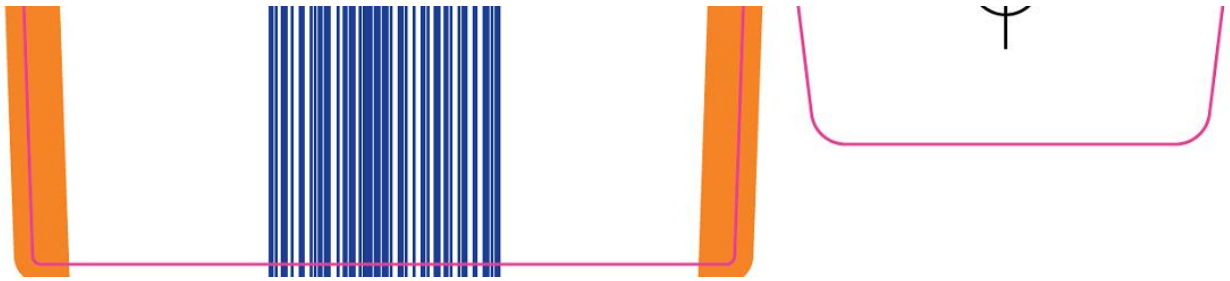
Dosing cup included

# PARENTS:

Learn about teen medicine abuse

[www.StopMedicineAbuse.org](http://www.StopMedicineAbuse.org)





## 12 HOUR COUGH RELIEF

dextromethorphan polistirex suspension

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55312-384
<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>HIGH FRUCTOSE CORN SYRUP</b> (UNII: XY6UN3QB6S)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>POVIDONES</b> (UNII: FZ989GH94E)	
<b>PROPYLPARABEN</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:55312-384-21	1 in 1 CARTON		
1		89 mL in 1 BOTTLE		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091135	09/14/2012	

**Labeler** - Western Family Foods Inc (192166072)

Revised: 11/2012

Western Family Foods Inc