# 12 HOUR COUGH RELIEF- dextromethorphan hydrobromide 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



TAMPER EVIDENT:

Do not use if carton is opened or neckband imprinted with

"sealed for your protection" is broken or missing.





# 12 HOUR 12 HOUR COUGH RELIEF

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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







DEXTROMETHORPHAN POESPENSION
EXTENDED-RELEASE ORAL SUSPENSION
EXTE

Contains no fever reducer or
Alcohol-free
Orange-Flavored Liquid

3 FL OZ (89 mL)







Proudly Distributed by





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12 years of age and over	not to exceed 20 mL in 24 hours
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12 years of age	not to exceed 10 mL in 24 hours
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6 years of age	not to exceed 5 mL in 24 hours
children under 4 years of age	do not use

# Other information

- store at 20° to 25°C (68° to 77°F) dosing cup provided

# ■ each 5 mL contains: sodium 5 mg

# 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	10 mL	
to adult	EVERY 12 HOURS	
6 to	5 mL	
under 12	EVERY 12 HOURS	
4 to	2.5 mL	
under 6	EVERY 12 HOURS	
Under 4	Do not use	

See back panel for full dosing directions.



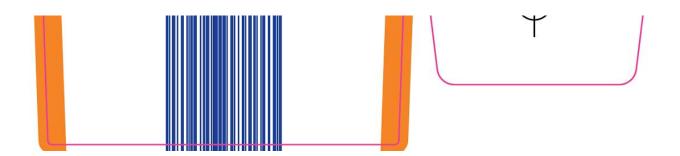
# PARENTS:

Learn about teen medicine abuse

www.StopMedicineAbuse.org







# 12 HOUR COUGH RELIEF

dextromethorphan polistirex suspension

Product Information			
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:55312-384
Route of Administration	ORAL	DEA Schedule	

l	Active Ingredient/Active Moiety			
l	Ingredient Name	Basis of Strength	Strength	
ı	<b>DEXTRO METHO RPHAN HYDRO BRO MIDE</b> (DEXTRO METHO RPHAN)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 5 mL	

Inactive Ingredients				
Ingredient Name	Strength			
POLISTIREX				
HIGH FRUCTOSE CORN SYRUP				
GLYCERIN				
METHYLPARABEN				
POLYSORBATE 80				
POVIDONES				
PROPYLPARABEN				
WATER				
SO DIUM METABISULFITE				
SODIUM POLYSTYRENE SULFONATE				
SUCROSE				
TARTARIC ACID				
TRAGACANTH				
TRIACETIN				
XANTHAN GUM				

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

P	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