CAREONE COUGH DM- dextromethorphan hydrobromide suspension American Sales Company

American Sales Company 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

Package/Label Principal Display Panel

Compare to the Active Ingredient in Delsym®

COUGH DM

DEXTROMETHORPHAN POLISTIREX

EXTENDED-RELEASE ORAL SUSPENSION

COUGH SUPPRESSANT

12 HOUR COUGH RELIEF

Orange-Flavored Liquid

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

Dosing Cup Included

Alcohol-free

CAREONE®



TAMPER EVIDENT:

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



Compare to the Active Ingredient in Delsym®*

CAREONE®

DEXTROMETHORPHAN POLISTIREX EXTENDED-RELEASE ORAL SUSPENSION COUGH SUPPRESSANT



12 Hour Cough Relief

Orange-Flavored Liquid

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

Dosing Cup Included Alcohol-free

3 FL OZ (89 ml)







DEXTROMETHORPHAN POLISTIREX EXTENDED-RELEASE ORAL SUSPENSION COUGH SUPPRESSANT

12 Hour Cough Relief

Orange-Flavored Liquid Contains No Fever Reduce or Pain Reliever Dosing Cup Included Alcohol-free



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4201 WALDEN AVE.
LANCASTER, NY 14086
1-877-846-9949
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Quality guaranteed or
your money back.

LOT NO.

EXP.

: 38421 D4 C1



Drug Facts

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*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.



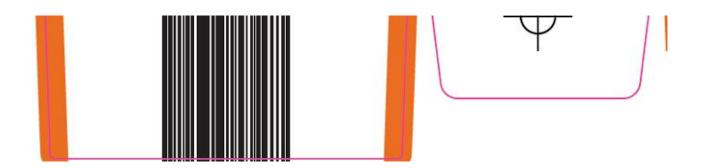
PARENTS:

Learn about teen medicine abuse

www.StopMedicineAbuse.org







CAREONE COUGH DM

dextromethorphan polistirex suspension

Product Information			
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:41520-384

Route of Administration ORAL DEA Schedule

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
DEXTROMETHORPHAN HYDROBROMIDE (DEXTROMETHORPHAN)	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:41520-384-21	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	08/30/2012	

Labeler - American Sales Company (809183973)

Revised: 11/2012 American Sales Company