COUGH DM- dextromethorphan polistirex suspension Major Pharmaceuticals

Major Pharmaceuticals Cough DM 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	
adults and children 12 years of age and over	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

Cough DM

Dextromethorphan Polistirex Extended-Release Oral Suspension

Cough Suppressant

12 HOUR COUGH RELIEF

Dosing Cup Included

Orange-Flavored Liquid

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

COMPARE TO the Active Ingredient of DELSYM®

Alcohol-free

Cough DM

Dextromethorphan Polistirex Extended-Release Oral Suspension

Cough Suppressant

TAMPER EVIDENT:

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



NDC 0904-6312-56



Cough DM

Dextromethorphan Polistirex Extended-Release Oral Suspension

Cough Suppressant

HOUR COUGH

Dosing Cup Included

RELIEF

Orange-Flavored Liquid

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

COMPARE TO the Active Ingredient of DELSYM®*

3FLOZ (89 mL)



Alcohol-free

ACTUAL SIZE



NDC 0904-6312-56

MAJOR Cough DM

Dextromethorphan Polistirex Extended-Release Oral Suspension Cough Suppressant

> HOUR HOUR RELIE

Dosing Cup Included

Contains No Fever Reducer or Pain Reliever

Alcohol-free • Orange-Flavored Liquid

3FLOZ(89mL)



Distributed by MAJOR®



PHARMACEUTICALS 31778 Enterprise Drive Livonia, MI 48150 USA M-05 REV. 07/12 Re-Order No. 014469

LOT NO.

EXP.

: 38421 5C C1



PWAJOR.

Drug Facts

Active ingredient (in each 5 mL)

Purpose

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Directions ■ shake bottle well before use

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adults and children	10 mL every 12 hours,
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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
children under 4 years of age	do not use

Other information

■ store at 20° to 25°C (68° to 77°F)

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

Drug Facts (continued)

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

C Questions or comments? 1-800-719-9260

Gluten Free

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.



*Major® Cough DM is not manufactured or distributed by Reckitt Benckiser Inc., distributor of Delsym®.

Dosing cup included

Learn about teen medicine abuse

www.StopMedicineAbuse.org







COUGH DM

dextromethorphan polistirex suspension

ı	Product Information			
ı	Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0904-6312

Route of Administration ORAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
DEXTRO METHO RPHAN HYDRO BRO MIDE (UNII: 9 D2RTI9 KYH)	DEXTROMETHORPHAN	30 mg		
(DEXTROMETHORPHAN - UNII:7355X3ROTS)	HYDROBROMIDE	in 5 mL		

Inactive Ingredients				
Ingredient Name	Strength			
POLISTIREX (UNII: 5H9 W9 GTW27)				
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)				
GLYCERIN (UNII: PDC6A3C0OX)				
METHYLPARABEN (UNII: A2I8 C7HI9 T)				
POLYSORBATE 80 (UNII: 6OZP39ZG8H)				
PO VIDO NES (UNII: FZ989 GH9 4E)				
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	Marketing Start Date	Marketing End Date
1	NDC:0904-6312-56	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	09/06/2012	

Labeler - Major Pharmaceuticals (191427277)

Revised: 11/2012 Major Pharmaceuticals