

LEADER COUGH DM- dextromethorphan polistirex suspension
Cardinal Health

Cardinal Health 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 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

Compare to Delsym® active ingredient

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

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 37205-697-21



Compare to
Delsym®
active ingredient*

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



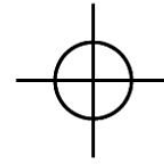
Alcohol-Free



3 FL OZ (89 mL)



DISTRIBUTED BY CARDINAL HEALTH
DUBLIN, OHIO 43017
CIN 4577920 www.myleader.com
1-800-200-6313



ACTUAL SIZE



NDC 37205-697-21



Cough DM

Dextromethorphan Polistirex
Extended-Release Oral Suspension
Cough Suppressant

12 Hour Cough Relief

Dosing Cup Included

Contains No Fever Reducer or Pain Reliever

Orange-Flavored Liquid

Alcohol-Free

3 FL OZ (89 mL)



0 96295 12271 8

All **Leader**® Brand products are
100% satisfaction guaranteed
or return to place of purchase
for a full refund.

LOT NO.

EXP.

: 38421 E9 C1





Drug Facts

Active ingredient (in each 5 mL)

Dextromethorphan polistirex equivalent to

30 mg dextromethorphan hydrobromide, USP.....Cough suppressant

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

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

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

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 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

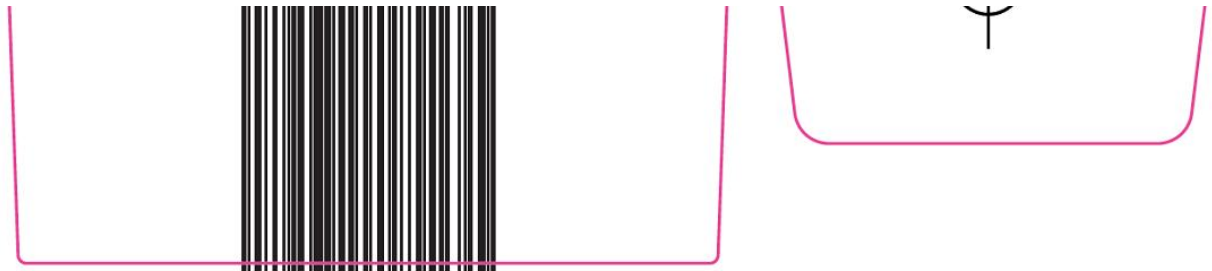
*This product is not manufactured or distributed by Reckitt Benckiser Inc., distributor of Delsym®.

PARENTS:

Learn about teen medicine abuse

www.StopMedicineAbuse.org





LEADER COUGH DM

dextromethorphan polistirex suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37205-697
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
POLISTIREX (UNII: 5H9W9GTW27)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POVIDONES (UNII: FZ989GH94E)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
SODIUM POLYSTYRENE SULFONATE (UNII: 1699G8679Z)	
SUCROSE (UNII: C151H8M554)	
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:37205-697-21	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	ANDA09 1135	09/13/20 12	

Labeler - Cardinal Health (097537435)

Revised: 11/2012

Cardinal Health