

DELSYM- dextromethorphan polistirex syrup
Rebel Distributors Corp

Drug Facts

Active ingredient

Dextromethorphan Polistirex

Purpose

Use(s)

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

Keep Out of Reach of Children

Uses

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Warnings

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Do not use

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.

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)

Ask a doctor or pharmacist before use if you are

When using this product

Stop use and ask a doctor if

Stop use and ask a doctor if 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

Keep out of reach of children

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

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 a doctor

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

Drug Facts

Distributed by: Reckitt Benckiser Inc., Parsippany, NJ 07054-0224 ©RBI 2009

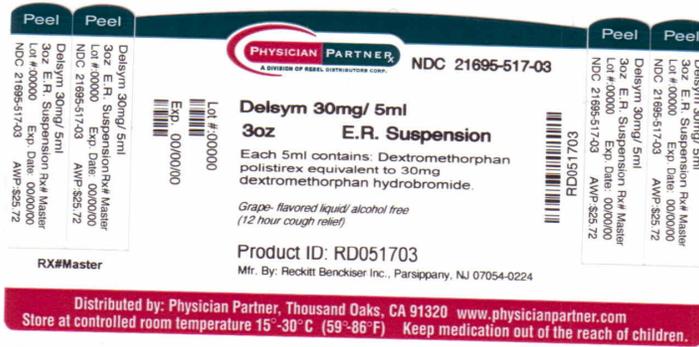
Inactive ingredients

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citric acid anhydrous, D&C Red #33, edetate disodium, ethylcellulose, FD&C Blue #1, flavor, high fructose corn syrup, methylparaben, polyethylene glycol 3350, polysorbate 80, propylene glycol, propylparaben,

purified water, sucrose, tragacanth, vegetable oil, xanthan gum

Package/Label Principal Display Panel



Package/Label Principal Display Panel



DELSYM

dextromethorphan polistirex syrup

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21695-517(NDC:63824-171)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ETHYLCELLULOSES (UNII: 7Z8S9VYZ4B)	

FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SUCROSE (UNII: C151H8M554)	
TRAGACANTH (UNII: 2944357O2O)	
CORN OIL (UNII: 8470G57WFM)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21695-517-30	90 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA018658	09/04/2009	

DELSYM

dextromethorphan polistirex syrup

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Labeler - Rebel Distributors Corp (118802834)

Establishment

Name	Address	ID/FEI	Business Operations
Rebel Distributors Corp		118802834	RELABEL, REPACK

Revised: 1/2011

Rebel Distributors Corp