DEXTROMETHORPHAN POLISTIREX EXTENDED RELEASE- dextromethorphan polistirex suspension Bryant Ranch Prepack

Perrigo Dextromethorphan Polistirex Extended-Release Oral Suspension Drug Facts

Active ingredient (in each 5 mL)

Dextromethorphan polistirex equivalent to 30 mg dextromethorphan hydrobromide

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

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

HOW SUPPLIED

Dextromethorphan Polistirex Extended-Release Oral Suspension

NDC 72162-2281-2: 89 mL in a BOTTLE

Repackaged/Relabeled by:

Bryant Ranch Prepack, Inc.

Dextromethorphan Polistirex Extended-Release Oral Suspension



Active Ingredient (in each 5 mL)

Destromethorphan polisitive equivalent to 30 mg dextromethorphan polisitive equivalent to 130 mg dextromethorphan hydrobromide.

See 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 coidase 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 metabisulfits, a sulfite that may cause ellegic-type reactions. Ask a doctor before use if you have "rhonic cough that lasts as occurs with smoking, astima or emphysema "cough that may report side effects to FDA at 1-80-FDA-11889 "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 wavy (1-800-222-11222).

Other Information

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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, (adultis 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; 2.5 mL every 12 hours, not to exceed 5 mL in 24 hours) (children under 4 years of age; 2.5 mL every 12 hours, not to exceed 5 mL in 24 hours) (children under 4 years)

vears of age; 2.5 mL every 12.5 mL of age; do not use).

Inactive Ingredients
D&C Red #30 aluminum lake, D&C Yellow #10 aluminum lake, flavor, glycerin, high fructo
com syrup, meltyparaben, polysorbate 80, polyvinyl acetate, povidore, propylparaben,
purified water, sodium metabsuffle, sodium polystyrene sulfonate, sucrose, tartaric acid,
tragacarth gum, tracetin, zanthan gum.

NDC 72162-2281-2

Dextromethorphan
Polistirex
Extended-Release
Oral Suspension

30 mg/5 mL



3 FL OZ (89 mL)

Relabeled by: Bryant Ranch Prepack, Inc. Burbank, CA 91504 USA



Extended Label

SHAKE WELL Measure only with	SING . BEFORE USE. dosing cup provided. up with other products.
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

DEXTROMETHORPHAN POLISTIREX EXTENDED RELEASE

dextromethorphan polistirex suspension

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72162-2281(NDC:45802-433)	
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 Strengt		
POLISTIREX (UNII: 5H9W9GTW27)		
D&C RED NO. 30 (UNII: 2S42T2808B)		

D&C YELLOW NO. 10 (UNII: 35SW5USQ3G) **GLYCERIN** (UNII: PDC6A3C0OX) HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S) METHYLPARABEN (UNII: A2I8C7HI9T) POLYSORBATE 80 (UNII: 60ZP39ZG8H) POLYVINYL ACETATE (UNII: 32K497ZK2U) POVIDONE, UNSPECIFIED (UNII: FZ989GH94E) PROPYLPARABEN (UNII: Z8IX2SC10H) WATER (UNII: 059QF0KO0R) **SODIUM METABISULFITE** (UNII: 4VON5FNS3C) **SODIUM POLYSTYRENE SULFONATE** (UNII: 1699G8679Z) SUCROSE (UNII: C151H8M554) TARTARIC ACID (UNII: W4888I119H) **TRAGACANTH** (UNII: 2944357020) 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:72162- 2281-2	1 in 1 CARTON	04/30/2024		
1	89 mL in 1 BOTTLE; Type 0: Not a Combination Product			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091135	09/10/2012	

Labeler - Bryant Ranch Prepack (171714327)

Registrant - Bryant Ranch Prepack (171714327)

Establishment			
Name	Address	ID/FEI	Business Operations
Bryant Ranch Prepack		171714327	REPACK(72162-2281), RELABEL(72162-2281)

Revised: 4/2024 Bryant Ranch Prepack