SIGNATURE CARE COUGH RELIEF- dextromethorphan polistirex suspension, extended release Safeway

Better Living Brands LLC Cough Relief 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 a doctor

adults and children 12	10 mL every 12 hours, not to exceed 20
years of age and over	mL in 24 hours
children 6 to under 12	5 mL every 12 hours, not to exceed 10
years of age	mL in 24 hours
children 4 to under 6 years	2.5 mL every 12 hours, not to exceed 5
of age	mL in 24 hours
children under 4 years of	do not use
age	

Other information

- each 5 mL contains: sodium 5 mg
- store at 20° to 25°C (68° to 77°F)
- dosing cup provided

Inactive ingredients

artificial grape flavor, D&C Red #30 aluminum lake, FD&C Blue #1 aluminum lake, 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

Quality Guaranteed

12 HOUR

Cough Relief

DEXTROMETHORPHAN POLISTIREX EXTENDED-RELEASE ORAL SUSPENSION

Cough Suppressant

GRAPE FLAVORED LIQUID

Day or Night

Alcohol-free

3 FL OZ (89 mL)

Dosing Cup Included

CONTAINS SODIUM METABISULFITE, A SULFITE THAT MAY CAUSE ALLERGIC-TYPE REACTIONS



SIGNATURE CARE COUGH RELIEF

dextromethorphan polistirex suspension, extended release

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21130-520
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	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
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)		
D&C RED NO. 30 (UNII: 2S42T2808B)		

Product Characteristics			
Color	PURPLE	Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

F	Packaging			
#	tem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21130-520- 21	1 in 1 CARTON	07/08/2021	
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	07/08/2021	

Labeler - Safeway (009137209)

Revised: 7/2021 Safeway