

COUGH RELIEF- dextromethorphan polistirex suspension

Safeway

Safeway Inc. 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?

1-888-723-3929

Package/Label Principal Display Panel

12 HOUR

Cough Relief

Dextromethorphan Polistirex Extended-Release Oral Suspension

Cough Suppressant

ORANGE-FLAVORED LIQUID

Compare to Delsym® active ingredient

Alcohol-free

Dosing cup included

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

3 FL OZ (89 mL)

OUR PROMISE

QUALITY & SATISFACTION

100% GUARANTEED

OR YOUR MONEY BACK.

TAMPER EVIDENT:

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

NDC 21130-402-21



Quality Guaranteed

12 HOUR Cough Relief

Dextromethorphan Polistirex
Extended-Release Oral Suspension
Cough Suppressant

ORANGE-FLAVORED LIQUID



Compare to
Delsym®
active ingredient*

- Alcohol-free
- Dosing cup included

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

3 FL OZ (89 mL)

S 1872

RD 14042



ACTUAL SIZE



NDC 21130-402-21



Quality Guaranteed

12 HOUR Cough Relief

Dextromethorphan Polistirex
Extended-Release Oral Suspension
Cough Suppressant

ORANGE-FLAVORED LIQUID



Alcohol-free

- Contains no fever reducer or pain reliever
- Dosing cup included

3 FL OZ (89 mL)



LOT NO.

EXP.

: 38421 15 C2



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

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

DISTRIBUTED BY SAFEWAY INC.
P.O. BOX 99, PLEASANTON,
CA 94566-0009
1-888-SAFEWAY
www.safeway.com

PARENTS:

Learn about teen medicine abuse

www.StopMedicineAbuse.org





COUGH RELIEF

dextromethorphan polistirex suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21130-402
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)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POVIDONES (UNII: FZ989GH94E)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0K00R)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
SODIUM POLYSTYRENE SULFONATE (UNII: 1699G8679Z)	
SUCROSE (UNII: C15IH8M554)	
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:21130-402-21	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	ANDA091135	03/18/2014	

Labeler - Safeway (009137209)

Revised: 3/2014

Safeway