

**HEALTHY ACCENTS COUGH RELIEF- dextromethorphan hydrobromide suspension
DZA Brands LLC**

DZA Brands, LLC Cough Relief 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?

1-866-322-2439

Package/Label Principal Display Panel

cough relief

dextromethorphan polistirex

extended-release oral suspension

cough suppressant

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

Compare to Delsym® active ingredient

orange-flavored liquid

12 HOUR COUGH RELIEF

dosing cup included

alcohol-free

healthy accents®

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

NDC 55316-384-21

healthy accents®

cough relief

dextromethorphan polistirex
extended-release oral suspension
cough suppressant

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

Compare to Delsym®
active ingredient

orange-flavored liquid



3 FL OZ (89mL)

dosing cup included

alcohol-free



actual size



healthy accents®
cough relief
dextromethorphan polistirex
extended-release oral suspension
cough suppressant
contains no fever reducer
or pain reliever
orange-flavored liquid
dosing cup included
3 FL OZ (89mL) alcohol-free



DISTRIBUTED BY: DZA BRANDS, LLC
Salisbury, NC 28147 / Scarborough, ME 04074
For product questions or concerns contact us at 1-866-322-2439.
Please include UPC number and code from package.



7 25439 97645 9



LOT NO.

EXP.

: 38421 HA 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?

1-866-322-2439

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

PARENTS:

Learn about teen medicine abuse

www.StopMedicineAbuse.org





HEALTHY ACCENTS COUGH RELIEF

dextromethorphan polistirex suspension

Product Information

Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:55316-384
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (DEXTROMETHORPHAN)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
POLISTIREX	
HIGH FRUCTOSE CORN SYRUP	
GLYCERIN	
METHYL PARABEN	
POLYSORBATE 80	
POVIDONES	
PROPYL PARABEN	
WATER	
SODIUM METABISULFITE	
SODIUM POLYSTYRENE SULFONATE	
SUCROSE	
TARTARIC ACID	
TRAGACANTH	
TRIACETIN	
XANTHAN GUM	

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:55316-384-21	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	12/04/20 12	

Labeler - DZA Brands LLC (090322194)

Revised: 4/2013

DZA Brands LLC