COUGH RELIEF ADULT- dextromethorphan hbr liquid TOP CARE (Topco Associates LLC)

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active ingredient (in each 5 mL)

Dextromethorphan HBr 15 mg

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.

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

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.

When using this product, do not use more than directed

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 (1-800-222-1222) right away.

Directions

- take recommended dosage or as directed by a doctor
- measure only with dosing cup provided. Do not use any other dosing device
- keep dosing cup with product
- shake well before using
- mL=milliliter

age	dose
adults and children 12 years and	10 mL every 6-8 hours not to exceed 4 doses in 24
over	hours,
children 6 to 11 years of age	5 mL every 6-8 hours not to exceed 4 doses in 24
children o to 11 years or age	hours
children under 6 years of age	do not use

Other information

- each 5 mL contains: sodium 3 mg
- store between 20-25°C (68°-77°F). Do not refrigerate.

Inactive ingredients

anhydrous citric acid, disodium EDTA, FD&C yellow #6, flavor, glycerin, high fructose corn syrup, hydroxyethyl cellulose, polyethylene glycol, propylene glycol, purified water, sodium benzoate, sucralose, sucrose, xanthan gum

Questions or comments?

Call toll free 1-888-423-0139

Principal Display Panel

Cough Relief

DEXTROMETHORPHAN HBr 15 mg

COUGH SUPPRESSANT

RELIEF OF:

- Cough
- Minor Throat & Bronchial Irritation
- Impulse to cough

6-8 HOUR RELIEF

FOR ADULTS

FOR AGES 6+

ORANGE FLAVOR

FL OZ (mL)

Dosing Cup Included

TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF PRINTED SAFETY SEAL AROUND BOTTLE OR UNDER CAP IS BROKEN OR MISSING.

DISTRIBUTED BY TOPCO ASSOCIATES LLC

ELK GROVE VILLAGE, IL 60007

topcare@topco.com

www.topcarebrand.com

Package Label

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Dextromethorphan HBr 15 mg.. ..Cough suppressan

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Drug Facts (continued)

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information or call 1-888-423-0139





Cough Relief

DEXTROMETHORPHAN HBr 15 mg COUGH SUPPRESSANT

RELIEF OF:

- Cough
- Minor Throat & **Bronchial Irritation**
- Impulse to Cough



FOR ADULTS FOR AGES 6+



4 FL OZ (118 mL)

ALCOHOL-FREE



PLD-J258C FC004555

Lot No .:

TOPCARE HEALTH Cough Relief

COUGH RELIEF ADULT

dextromethorphan hbr liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:36800-509

Route of Administration ORAL

Active Ingredient/Active Moiety

Basis of Strength Ingredient Name Strength

DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)

DEXTROMETHORPHAN HYDROBROMIDE

15 mg in 5 mL

Inactive Ingredients		
Ingredient Name	Strength	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)		
WATER (UNII: 059QF0KO0R)		
EDETATE DISODIUM (UNII: 7FLD91C86K)		
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)		
GLYCERIN (UNII: PDC6A3C0OX)		
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)		
HYDROXYETHYL CELLULOSE (1500 MPA.S AT 1%) (UNII: L605B5892V)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
SUCRALOSE (UNII: 96K6UQ3ZD4)		
SUCROSE (UNII: C151H8M554)		
XANTHAN GUM (UNII: TTV12P4NEE)		

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	ORANGE	Imprint Code	
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800- 509-04	1 in 1 BOX	03/31/2016	
1		118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part341	03/31/2016		

Labeler - TOP CARE (Topco Associates LLC) (006935977)

Revised: 11/2022 TOP CARE (Topco Associates LLC)