COUGH RELIEF COUGH SUPPRESSANT- dextromethorphan hbr liquid QUALITY CHOICE (Chain Drug Marketing Association)

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, 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 no to exceed 4 doses in	
over	24 hours	
children 6 to 11 years of age	5 mL every 6-8 hours not to exceed 4 doses in	
	24 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, edetate disodium, 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 1-248-449-9300 Monday-Friday 9AM-5PM EST

Principal Display Panel

COUGH RELIEF

Cough Suppressant

Dextromehtorphan HBr 15 mg

Cough Suppressant

For Ages 6 & Over

6-8 Hour Relief

Alcohol Free

Orange Flavor

FL OZ (mL)

Contains no fever reducer or pain reliever

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 C.D.M.A., Inc,©

43157 W. Nine Mile

Novi, MI 48376-0995

www.qualitychoice.com

Package Label



dextromethorphan hbr liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:63868-957

Route of Administration ORAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) DEXTROMETHORPHAN - UNII:7355X3ROTS) DEXTROMETHORPHAN | 15 mg | in 5 mL

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

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	ORANGE	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:63868- 957-04	1 in 1 BOX	07/31/2015	
1		118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information			
Marketing	Application Number or Monograph	Marketing Start	Marketing End

Category	Citation	Date	Date
OTC monograph final	part341	07/31/2015	

Labeler - QUALITY CHOICE (Chain Drug Marketing Association) (011920774)

Registrant - P & L Development, LLC (079765031)

Revised: 12/2022 QUALITY CHOICE (Chain Drug Marketing Association)