

COUNTERACT COUGH- dextromethorphan hbr. and guaifenesin syrup

Melaleuca, Inc.

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.

CounterAct Cough Content of Label

Active ingredients (in each 5 mL tsp)

Dextromethorphan HBr, USP 10 mg

Guaifenesin, USP 100 mg

Purpose

Dextromethorphan HBr, USP 10 mg.....Cough Suppressant

Guaifenesin, USP 100 mg.....Expectorant

Uses

- temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold
- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes

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

- cough that occurs with too much phlegm (mucus)
- cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis or emphysema

Stop use and ask a doctor if cough lasts for more than 7 days, comes back, or occurs with fever, rash or persistent headache. A persistent cough may be a sign 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.

Directions

- do not take more than 6 doses in any 24-hour period
- this adult product is not intended for use in children under 12 years of age

age	dose
adults and children 12 years and over	2 tsp every 4 hours
children under 12 years	do not use

Other information

- store at 20°-25°C (68°-77°F)

Inactive ingredients anhydrous citric acid, FD and C red no. 40, flavors, glycerin, high fructose corn

syrup, propylene glycol, purified water, saccharin sodium, sodium benzoate

Questions or comments?

1-800-282-3000

DO NOT USE IF PRINTED NECKBAND IS BROKEN OR MISSING

359-003 ELA18B-1 ELA18B

NDC 54473-080-04

SEE NEW DOSING DIRECTIONS

CounterAct[®]Cough

Cough Suppressant (Dextromethorphan HBr)
Expectorant (Guaifenesin)

For Effective Relief

- Controls Coughs
- Relieves Chest Congestion
- Non-Drowsy
- Alcohol-Free

**Wild Cherry
Flavor**

For Adults • Ages 12 & Over

4 FL OZ (118 mL)



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Dist. by: Melaleuca, Inc.
Idaho Falls, ID 83402-6003
To order: 1-800-282-3000
www.melaleuca.com
#1412 02/09U

**CODE
AREA**

• no varnish • no color

: 35926 MB F4



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- Non-Drowsy
- Alcohol-Free

RELIABLE and EFFECTIVE formula.
NON-DROWSY and NON-NARCOTIC formula.

PARENTS:
Learn about teen medicine abuse

www.StopMedicineAbuse.org



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Safety Sealed

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(Dextromethorphan HBr)
Expectorant (Guaifenesin)

NDC 54473-080-04

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Wild Cherry
Flavor



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Ages 12 & Over

4 FL OZ (118 mL)

LOT NO.

EXP. **Code Area**

: 35926 MB C4

EFB 839

359-003

NDC 54473-080-04

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54473-080
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 5 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	red (Orange-red)	Score	
Shape		Size	
Flavor	CHERRY (Wild Cherry)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54473-080-04	1 in 1 BOX		
1		118 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	08/28/2009	

Labeler - Melaleuca, Inc. (139760102)

