

## **COUGH CHILDRENS- dextromethorphan hydrobromide, guaifenesin solution**

**Walgreen Company**

*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.*

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### **Walgreen Co. Cough Drug Facts**

#### **Active ingredients (in each 5 mL)**

Dextromethorphan HBr 5 mg

Guaifenesin 100 mg

#### **Purpose**

Cough suppressant

Expectorant

#### **Uses**

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
- temporarily relieves:
- cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants
- the intensity of coughing
- the impulse to cough to help your child get to sleep

#### **Warnings**

##### **Do not use**

in a child who is 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 child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.

##### **Ask a doctor before use if the child has**

- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such as occurs with asthma

##### **Stop use and ask a doctor if**

cough lasts more than 7 days, comes back, or occurs with fever, rash, or persistent headache. These could be signs of a serious condition.

##### **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

- do not take more than 6 doses in any 24-hour period
- measure only with dosing cup provided
- do not use dosing cup with other products
- mL = milliliter

Age	Dose
children 6 years to under 12 years	5 mL - 10 mL every 4 hours
children 4 years to under 6 years	2.5 mL – 5 mL every 4 hours
children under 4 years	do not use

## Other information

- do not use if printed neckband is broken or missing
- store at 20-25°C (68-77°F)
- do not refrigerate
- dosing cup provided

## Inactive ingredients

acesulfame potassium, anhydrous citric acid, D&C red #33, FD&C red #40, flavor, glycerin, maltitol solution, propylene glycol, purified water, saccharin sodium, sodium benzoate, sorbitol solution, xanthan gum

## Questions or comments?

1-800-719-9260

## Principal Display Panel

Compare to Children's Mucinex® Cough active ingredients

children's Cough

DEXTROMETHORPHAN HBr / COUGH SUPPRESSANT

GUAIFENESIN / EXPECTORANT

ALCOHOL FREE

Breaks up the mucus that causes congestion while controlling coughs

AGES 4 – 12 YEARS

CHERRY FLAVOR

4 FL OZ (118 mL)



## COUGH CHILDRENS

dextromethorphan hydrobromide, guaifenesin solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0363-0419
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

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

### Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
XANTHAN GUM (UNII: TTV12P4NEE)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	

### Product Characteristics

Color	RED (Dark Red)	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-0419-26	1 in 1 CARTON	08/03/2007	
1		118 mL in 1 BOTTLE; 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	04/09/1993	

**Labeler** - Walgreen Company (008965063)