

**CHILDRENS ROBITUSSIN COUGH LONG-ACTING- dextromethorphan hydrobromide liquid**

**GlaxoSmithKline Consumer Healthcare Holdings (US) 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.*

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**DRUG FACTS**

**Active ingredient (in each 10 ml)**

Dextromethorphan HBr, USP 15 mg

**Purpose**

Cough suppressant

**Use**

temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold

**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**

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

**Stop use and ask a doctor if** cough lasts more than 7 days, comes back, or is accompanied by fever, rash, or persistent headache. 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.

**Directions**

1. measure only with dosing cup provided
2. keep dosing cup with product
3. ml = milliliter
4. do not take more than 4 doses in any 24-hour period

<b>age</b>	<b>dose</b>
children under 4 years	do not use
children 4 to under 6 years	5 ml every 6 - 8 hours
children 6 to under 12 years	10 ml every 6 to 8 hours
adults and children 12 years and older	20 ml every 6 to 8 hours

### ***Other information***

1. **each 10 ml contains:** sodium 11 mg
2. store at 20-25°C (68-77°F)

### ***Inactive ingredients***

anhydrous citric acid, artificial flavor, FD&C red no. 40, glycerin, high fructose corn syrup, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium chloride, sodium citrate

### ***Questions or comments?***

Call weekdays from 9 AM to 5 PM EST at **1-800-762-4675**

Distributed by:  
Pfizer, Madison, NJ 07940 USA

For most recent product information, visit  
[www.robitussin.com](http://www.robitussin.com)

## **PRINCIPAL DISPLAY PANEL**

***NEW***

***Dosing  
Information***

**Children's  
Robitussin®  
NOW FOR AGES 4 & OVER**

**Cough**

**Long-Acting**

**DEXTROMETHORPHAN HBr (Cough Suppressant)**

## Relieves:

✓ Cough Up to **8 Hours**

**Alcohol-Free**

**fruit  
punch  
flavor**

4 FL OZ  
(118 ml)



**CHILDRENS ROBITUSSIN COUGH LONG-ACTING**

dextromethorphan hydrobromide liquid

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0031-8694
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	7.5 mg in 5 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>HIGH FRUCTOSE CORN SYRUP</b> (UNII: XY6UN3QB6S)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>SODIUM CITRATE, UNSPECIFIED FORM</b> (UNII: 1Q73Q2JULR)	

**Product Characteristics**

<b>Color</b>	RED (bright red)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	FRUIT PUNCH	<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0031-8694-12	1 in 1 CARTON	07/01/2015	
1		118 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	01/01/2004	

**Labeler** - GlaxoSmithKline Consumer Healthcare Holdings (US) LLC (079944263)

Revised: 12/2022

GlaxoSmithKline Consumer Healthcare Holdings (US) LLC