

CHILDRENS ROBITUSSIN COUGH LONG-ACTING- dextromethorphan hydrobromide liquid
Wyeth Consumer Healthcare 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.

Children's Robitussin® Cough Long-Acting

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

- cough that occurs with too much phlegm (mucus)
- 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

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

age	dose
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

- **each 10 ml contains:** sodium 11 mg
- 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

PRINCIPAL DISPLAY PANEL - 118 ml Bottle Label

Children's
Robitussin®
AGES 4 & OVER

Cough

Long-Acting

DEXTROMETHORPHAN HBr (Cough Suppressant)

Relieves Cough up to **8 Hours**

Alcohol-Free

4 FL OZ (118 ml)

<p>Packaged with Tamper-Evident bottle cap. Do Not Use if breakable ring is separated or missing.</p> <p>Active ingredient (in each 10 ml): Dextromethorphan HBr, USP 15 mg 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: cough that occurs with too much phlegm (mucus); 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. Other information: Each 10 ml contains: sodium 11 mg. Store at 20-25°C (68-77°F).</p>	<p>Children's Robitussin® AGES 4 & OVER</p> <p>Cough</p> <p>Long-Acting</p> <p>DEXTROMETHORPHAN HBr (Cough Suppressant)</p> <p>Relieves Cough up to 8 Hours</p> <p>Alcohol-Free 4 FL OZ (118 ml)</p>	<p>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. Directions: Measure only with dosing cup provided. Keep dosing cup with product. ml = milliliter. Do not take more than 4 doses in any 24-hour period.</p> <table border="1"><thead><tr><th>age</th><th>dose</th></tr></thead><tbody><tr><td>children under 4 years</td><td>do not use</td></tr><tr><td>children 4 to under 6 years</td><td>5 ml every 6 to 8 hours</td></tr><tr><td>children 6 to under 12 years</td><td>10 ml every 6 to 8 hours</td></tr><tr><td>adults and children 12 years and older</td><td>20 ml every 6 to 8 hours</td></tr></tbody></table> <p>Distributed by: Pfizer Madison, NJ 07940 USA © 2016 Pfizer Inc. For most recent product information, visit www.robitussin.com</p> <p>LOT: EXP: PAA076408</p>	age	dose	children under 4 years	do not use	children 4 to under 6 years	5 ml every 6 to 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
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PRINCIPAL DISPLAY PANEL - 118 ml Bottle Carton

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

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

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	7.5 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)	
WATER (UNII: 059QF0K00R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	

Product Characteristics

Color	RED (bright red)	Score	
Shape		Size	
Flavor	FRUIT PUNCH	Imprint Code	
Contains			

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 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	01/01/2004	

Labeler - Wyeth Consumer Healthcare LLC (828831730)

Revised: 12/2019

Wyeth Consumer Healthcare LLC