

**CHILDRENS ROBITUSSIN COUGH AND COLD LONG-ACTING- chlorpheniramine maleate,
dextrometorphan hbr liquid
Richmond Division of Wyeth**

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 AND COLD LONG-ACTING

Drug Facts

| <i>Active ingredients (in each 10 ml)</i> | <i>Purposes</i> |
|--|------------------------|
| Chlorpheniramine maleate, USP 2 mg | Antihistamine |
| Dextromethorphan HBr, USP 15 mg | Cough suppressant |

Uses

- temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold
- temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
 - runny nose
 - sneezing
 - itchy, watery eyes
 - itching of the nose or throat

Warnings

Do not use

- to sedate a child or to make a child sleepy
- 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

- trouble urinating due to an enlarged prostate gland
- glaucoma
- a cough that occurs with too much phlegm (mucus)
- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis or emphysema

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers

When using this product

- **do not use more than directed**
- marked drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

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 6 years | do not use |
| children 6 to under 12 years | 10 ml every 6 hours |
| adults and children 12 years and older | 20 ml every 6 hours |

Other information

- **each 10 ml contains:** sodium 6 mg
- store at 20-25°C (68-77°F)

Inactive ingredients

anhydrous citric acid, artificial & natural flavors, FD&C red no. 40, glycerin, lactic acid, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol solution, sucralose

Questions or comments?

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

Distributed by:

Pfizer, Madison, NJ 07940 USA

PRINCIPAL DISPLAY PANEL - 118 ml Bottle Carton

Children's

Robitussin®

AGES 6 & OVER

Cough & Cold

Long-Acting

CHLORPHENIRAMINE MALEATE (Antihistamine)

DEXTROMETHORPHAN HBr (Cough Suppressant)

Relieves:

- Cough Up to 8 Hours

☐ Runny Nose

Alcohol-Free

fruit
punch
flavor

4 FL OZ
(118 ml)

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**fruit
punch**



Children's Robitussin liquid is specially formulated to **provide soothing action, control your child's cough** plus relieve other cold symptoms.

Children's

Robitussin

AGES 6 & C

Cough & Co

Long-Acting

CHLORPHENIRAMINE MALEATE (Antihis
DEXTROMETHORPHAN HBr (Cough Supp

Should be 18 or older to purchase

PARENTS:

Learn about teen medicine abuse

FL OZ (

flavor

4 FL OZ
(118 ml)

www.StopMedicineAbuse.org

LOT:
EXP:

Packaged with Tamper-Evident bottle cap. Do Not Use
if breakable ring is separated or missing.

Children's

Robitussin®

AGES 6 & OVER

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Drug Facts (continued)

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chlorpheniramine maleate, dextrometorphan hbr liquid

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0031-8693 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------------------|----------------|
| CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U) | CHLORPHENIRAMINE MALEATE | 1 mg in 5 mL |
| DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RT9KYH) (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) | |

| | |
|--|--|
| LACTIC ACID, UNSPECIFIED FORM (UNII: 33X04XA5AT) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| WATER (UNII: 059QF0KO0R) | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | |
| SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR) | |
| SORBITOL (UNII: 506T60A25R) | |
| SUCRALOSE (UNII: 96K6UQ3ZD4) | |

Product Characteristics

| | | | |
|-----------------|------------------|---------------------|--|
| Color | RED (red liquid) | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:0031-8693-12 | 1 in 1 CARTON | 01/01/2004 | |
| 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 - Richmond Division of Wyeth (829390835)

Revised: 2/2019

Richmond Division of Wyeth