# CHILDRENS ROBITUSSIN COUGH AND COLD LONG-ACTING- chlorpheniramine maleate, dextrometrorphan 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.

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## CHILDREN'S ROBITUSSIN® COUGH AND COLD LONG-ACTING

## **Drug Facts**

| Active ingredients (in each 10 ml) | Purposes          |
|------------------------------------|-------------------|
| 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                    | 10 ml every 6 hours |
| years                                     | 3                   |
| adults and children 12<br>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<sup>®</sup>

**AGES 6 & OVER** 

Cough & Cold

Long-Acting

CHLORPHENIRAMINE MALEATE (Antihistamine)
DEXTROMETHORPHAN HBr (Cough Suppressant)

Relieves:

Ough Up to 8 Hours

Runny Nose

Alcohol-Free

fruit punch flavor

4 FL OZ (118 ml) Children's

## **Robitussin**

AGES 6 & OVER

## Cough & Cold

Long-Acting

Children's

# Robitussin

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DEXTROMETHORPHAN HBr (Cough Suppressant)

## Relieves:

- Cough Up to Hours
- ✓ Runny Nose Alcohol-Free



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

Robituss

AGES 6 & C

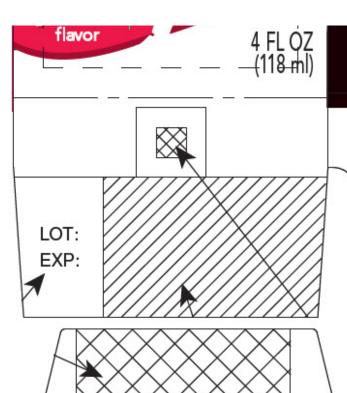
Cough & Co

ong-Acting

OURPHENIRAMINE MALEATE (Antihis Ouromethorphan HBr (Cough Supp

Should be 18 or older to purchase

PARENTS:



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

## Children's

## Robitussin

**AGES 6 & OVER** 

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## Drug Facts (continued)

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.

www.StopMedicineAbuse.org

If pregnant or breast-feeding, ask a health professional

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

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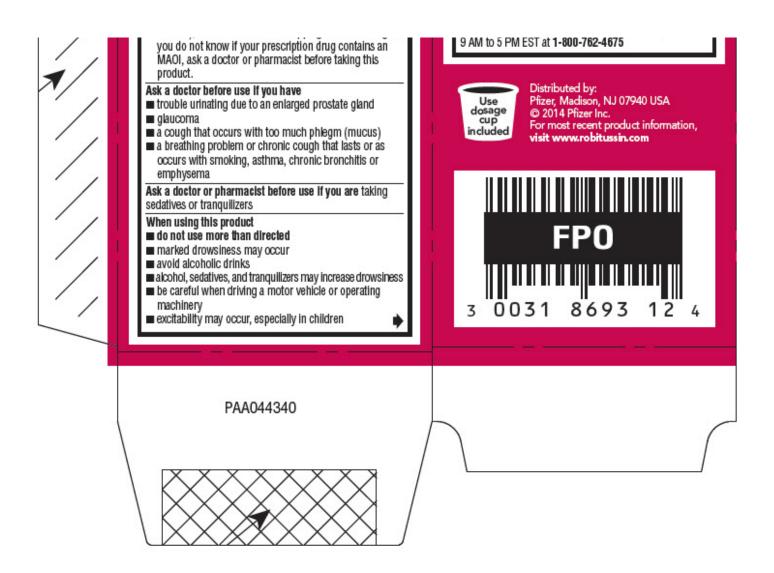
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**Questions or comments?** Call weekdays from



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chlorpheniramine maleate, dextrometrorphan 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<br>MALEATE      | 1 mg<br>in 5 mL   |  |  |
| <b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9 D2RTI9 KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN<br>HYDROBROMIDE | 7.5 mg<br>in 5 mL |  |  |

| Inactive Ingredients                      |          |  |
|-------------------------------------------|----------|--|
| Ingredient Name                           | Strength |  |
| ANHYDRO US 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                                   | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |  |
| 1 NDC:0031-8693-12 | 1 in 1 CARTON                                         | 0 1/0 1/20 0 4              |                           |  |
| 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                                  | 0 1/0 1/20 0 4       |                    |
|                       |                                          |                      |                    |

## **Labeler** - Richmond Division of Wyeth (829390835)

Revised: 2/2019 Richmond Division of Wyeth