

**CHILDREN COUGH AND COLD- chlorpheniramine maleate, dextromethorphan hbr, pseudoephedrine hcl liquid
RUGBY LABORATORIES**

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.

Active ingredient (in each 10 mL)

Chlorpheniramine maleate 2 mg

Dextromethorphan HBr 10 mg

Pseudoephedrine HCl 30 mg

Purpose

Antihistamine

Cough Suppressant

Nasal Decongestant

Uses temporarily relieves these symptoms of the common cold, hay fever or other upper respiratory allergies:

- cough
- runny nose
- nasal congestion
- sneezing
- itching of the nose or throat
- itchy, watery eyes

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 child has

- diabetes
- glaucoma
- thyroid disease
- heart disease
- high blood pressure
- cough that occurs with too much phlegm (mucus)
- a breathing problem such as chronic bronchitis
- chronic cough that lasts such as occurs with asthma or tranquilizers

When using this product

- do not use more than directed

- excitability may occur, especially in children
- drowsiness may occur
- sedatives and tranquilizers may increase drowsiness

Stop use and ask a doctor if

- the child gets nervous, dizzy or sleepless
- cough lasts more than 7 days, comes back or occurs with fever, rash or persistent headache. A persistent cough may be sign of a serious condition.
- Symptoms do not get better within 7 days or occur with fever

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

- dose may be repeated every 6 hours
- do not exceed 4 doses in a 24-hour period
- use enclosed dosage cup only. Do not use any other device.

Age	Dose
Children 6 to 11 years	2 TSP
Children under 6 years	Do not use

Inactive ingredients: artificial and natural cherry flavor, citric acid, FD&C red #40, methylparaben, propylene glycol, propylparaben, purified water, sodium citrate, sucralose

Questions or comments? 1-800-645-2158

Drug Facts

Active ingredients (in each 2 TSP (10mL)) Purpose

Chlorpheniramine maleate, USP 2mg.....Antihistamine

Dextromethorphan HBr., USP 10mg.....Cough suppressant

Pseudoephedrine HCl., USP 30mg.....Nasal decongestant

Uses temporarily relieves these symptoms of the common cold, hay fever or other upper respiratory allergies: • cough • runny nose • nasal congestion • sneezing • itching of the nose or throat • itchy, watery eyes

Warnings

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Lot#: _____

Exp. Date: _____



NDC 0536-1243-97

Children's Cough and Cold Liquid

Cherry Flavored

4 OZ (118 mL)

Drug Facts (continued)

Stop use and ask a doctor if

- the child gets nervous, dizzy or sleepless
- cough lasts more than 7 days, comes back or occurs with fever, rash or persistent headache. A persistent cough may be a sign of a serious condition.
- symptoms do not get better within 7 days or occur with fever

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

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Age	Dose
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Children under 6 years	Do not use

Other information store at room temperature 20°-25°C (68°-77°F)
TAMPER EVIDENT: Do not use if foil seal over bottle opening is torn, broken or missing.

Inactive ingredients artificial and natural cherry flavor, citric acid, FD&C red #40, methylparaben, propylene glycol, propylparaben, purified water, sodium citrate, sucralose.

Questions or comments? 1-800-645-2158

Code#L-154 Rev. 11/19 R-164 Re-order No. 370794



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Distributed by: RUGBY® LABORATORIES, 17177 N Laurel Park Drive, Suite 233, Livonia, MI 48152 www.rugbylaboratories.com

CHILDREN COUGH AND COLD
 chlorpheniramine maleate, dextromethorphan hbr, pseudoephedrine hcl liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-1243
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	2 mg in 10 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 10 mL
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	30 mg in 10 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-1243-97	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	08/01/2019	

Labeler - RUGBY LABORATORIES (079246066)