

**COUGH AND COLD- chlorpheniramine maleate and dextromethorphan hydrobromide liquid
Accudial Pharmaceutical, Inc.**

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
ACCUDIAL**

COUGH & COLD LONG-ACTING

Drug Facts

<i>Active ingredients (in each 5 mL tsp)</i>	<i>Purposes</i>
Chlorpheniramine maleate, USP 1 mg	Antihistamine
Dextromethorphan HBr, USP 7.5 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 the child has

- 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 the child is 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

- do not take more than 4 doses in any 24-hour period
- to find right dose, use rotating bottle label to dose by weight; otherwise, use chart below to dose by age
- specifically designed for use with enclosed dosing spoon. Use only enclosed dosing spoon to dose this product. Do not use any other dosing device

age	dose
under 6 years	do not use
6 to under 12 years	1-2 tsp. (5-10 mL) every 6 hours

Other information

- **each teaspoon contains:** sodium 2 mg
- store at 20°-25°C (68°-77°F)

Inactive ingredients

artificial flavor, citric acid, FD&C red #40, glycerin, purified water, sodium benzoate, sodium citrate, sorbitol, sucralose.

Questions?

877-434-2036

PRINCIPAL DISPLAY PANEL - 118 mL Carton

**CHILDREN'S
ACCUDIAL**

ROTATING DOSING LABEL

**Cough & Cold
Long-Acting**

**ACCURATE DOSING
BY WEIGHT**

**Chlorpheniramine Maleate
(Antihistamine)**

**Dextromethorphan HBr
(Cough Suppressant)**

RELIEVES

Cough: Up to 8 Hours

Runny Nose

For Ages 6 to under 12

Compares to Children's Robitussin® Cough & Cold Long-Acting.

FRUIT PUNCH FLAVOR

4 FL. OZ.
(118 mL)

NDC 45014-151-04



COUGH & COLD LONG-ACTING

Drug Facts (continued)

- marked drowsiness may occur
- avoid alcoholic drinks
- alcohol, anesthetics, 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

- do not take more than 4 doses in any 24-hour period
- to find right dose, use rotating bottle label to dose by weight; otherwise, use chart below to dose by age
- specifically designed for use with enclosed dosing spoon. Use only enclosed dosing spoon to dose this product. Do not use any other dosing device.

age	dose
under 6 years	do not use
6 to under 12 years	1-2 tsp. (5-10 mL) every 6 hours

Other information

- each teaspoon contains sodium 2 mg
- store at 20°-25°C (68°-77°F)

Inactive ingredients

artificial flavor, citric acid, FD&C red #40, glycerin, purified water, sodium benzoate, sodium citrate, sorbitol, sucralose.

Questions? 877-434-2036

Original Equipment Mfg'd by: ACCUDIAL, INC. 151-04



CHILDREN'S ACCUDIAL

Cough & Cold Long-Acting

FREE DOSING SPOON ENCLOSED.



CHILDREN'S ACCUDIAL

ROTATING DOSING LABEL

ACCURATE DOSING BY WEIGHT

Chlorpheniramine Maleate (Antihistamine)

Dextromethorphan HBr (Cough Suppressant)

RELIEVES **Cough: Up to 8 Hours**
Runny Nose

For Ages 6 to under 12

Compares to Children's Robitussin® Cough & Cold Long-Acting.



FRUIT PUNCH FLAVOR

4 FL. OZ. (118 mL)
NDC 45014-151-04



DO NOT USE FOR CHILDREN UNDER THE AGE OF 6 OR WEIGHING LESS THAN 45 LBS.



More than 92% of children are inaccurately dosed when taking over-the-counter medications. The Accudial® rotating label and dosing spoon are designed specifically to help solve this problem. Do not use if carton is opened, or if foil seal is broken or missing. See bottom of carton for expiration date.

INTRODUCTION BY



PHARMACEUTICAL, INC.

Pain South Services
FL 33410
Accudial@fhs.com

7 05109 64701 5

COUGH AND COLD

chlorpheniramine maleate and dextromethorphan hydrobromide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:450 14-151
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: 9D2RTI9KYH) (Dextromethorphan - UNII:7355X3ROTS)	Dextromethorphan Hydrobromide	7.5 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
Fruit (UNII: C2AIY4ERZC)	
Citric Acid Monohydrate (UNII: 2968PHW8QP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
Glycerin (UNII: PDC6A3C0OX)	
Water (UNII: 059QF0KO0R)	
Sodium Benzoate (UNII: OJ245FE5EU)	
Sodium Citrate (UNII: 1Q73Q2JULR)	
Sorbitol (UNII: 506T60A25R)	
Sucralose (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color	RED (Reddish-Pink) , PINK	Score	
Shape		Size	
Flavor	FRUIT PUNCH	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:450 14-151-04	118 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	11/25/2009	

Labeler - Accudial Pharmaceutical, Inc. (831999201)

