

ALLERGY- diphenhydramine hydrochloride 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

ALLERGY

Drug Facts

Active ingredient (in each 5 mL)¹

Diphenhydramine HCl 12.5 mg

¹ 5mL = one teaspoon

Purpose

Antihistamine

Uses

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 make a child sleepy
- with any other product containing diphenhydramine, even one used on skin

Ask a doctor before use if the child has

- a breathing problem such as chronic bronchitis
- glaucoma
- a sodium-restricted diet

Ask a doctor or pharmacist before use if the child is taking sedatives or tranquilizers

When using this product

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

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

Directions

- take every 4 to 6 hours
- do not take more than 6 doses in 24 hours
- 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

children under 2 years	do not use
children 2 to 5 years	do not use unless directed by a doctor
children 6 to under 12 years	5 mL to 10 mL (1 to 2 teaspoonfuls)

Other information

each teaspoon contains:

- **sodium 3 mg**
- store between 20°-25°C (68°-79°F). Protect from light. Store in outer carton until contents used.

Inactive ingredients

artificial flavor, citric acid, D&C red no. 33, FD&C red no. 40, glycerin, polysorbate 20, purified water, sodium benzoate, sodium citrate, sodium saccharin, sorbitol.

Questions?

877-434-2036

PRINCIPAL DISPLAY PANEL - 118 mL Carton

**CHILDREN'S
ACCUDIAL**

ROTATING DOSING LABEL

**ACCURATE DOSING
BY WEIGHT**

Diphenhydramine HCl

Oral Solution

Anthisamine

FOR RELIEF OF

Sneezing

Itchy, Watery Eyes

Runny Nose

Itchy Throat

For Ages 6 to under 12

Alcohol & Sugar Free

Compares to Children's

Benadryl® Allergy.

**CHERRY
FLAVOR**

4 FL. OZ.
(118 mL)
NDC 45014-140-04

Allergy



**CHILDREN'S
ACCUDIAL**

ALLERGY

Drug Facts

Active ingredient (in each 5 mL)*

Diphenhydramine HCl 12.5 mg	Antihistamine
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*See all ingredients

Uses

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ALLERGY

Drug Facts (continued)

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-232-1232)

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- do not take more than 6 doses in 24 hours
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**CHILDREN'S
ACCUDIAL**

Allergy

FREE DOSING SPOON ENCLOSED.

**CHILDREN'S
ACCUDIAL**

ROTATING DOSING LABEL

Allergy

ACCURATE DOSING BY WEIGHT

Diphenhydramine HCl Oral Solution
Antihistamine

FOR RELIEF OF

**Sneezing
Itchy, Watery Eyes
Runny Nose
Itchy Throat**

For Ages 6 to under 12

Alcohol & Sugar Free
Compared to Children's Benadryl® Allergy.



4 FL. OZ.
(118 mL)
NDC 45014-140-04

DO NOT USE FOR CHILDREN UNDER THE AGE OF 6 OR WEIGHING LESS THAN 44 LBS.



READ THESE LABELS TO SEE HOW TO USE THIS PRODUCT

Turn label and flip back bottle to see clear window and dose well. The window shows the correct weight of child weight a rotating dosing spoon to use.

More than 50% 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.

DISTRIBUTED BY

ACCUDIAL
PHARMACEUTICAL, INC.

Palm Beach Gardens, FL 33409
Accudial@Dove.com



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ALLERGY

diphenhydramine hydrochloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:450 14-140
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Diphenhydramine Hydrochloride (UNII: TC2D6JAD40) (Diphenhydramine - UNII:8GTS82S83M)	Diphenhydramine Hydrochloride	12.5 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
Citric Acid Monohydrate (UNII: 2968PHW8QP)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
Glycerin (UNII: PDC6A3C0OX)	
Polysorbate 20 (UNII: 7T1F30V5YH)	
Water (UNII: 059QF0KO0R)	
Sodium Benzoate (UNII: OJ245FE5EU)	
Sodium Citrate (UNII: 1Q73Q2JULR)	
Saccharin Sodium (UNII: SB8ZUX40TY)	
Sorbitol (UNII: 506T60A25R)	

Product Characteristics

Color	PINK	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:450 14-140-04	118 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	10/26/2009	

Labeler - Accudial Pharmaceutical, Inc. (831999201)