

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.

Allergy

Drug Facts

Active ingredient (in each 5 mL = 1 teaspoon)

Diphenhydramine, USP HCl 12.5 mg.

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.

Consult your pharmacist or health care provider for any appropriate, additional dosage delivery device necessary for use when a physician recommends a dose that is different than the doses that appear on the dosage delivery device that accompanies this product.

Age (yr)	Dose (TSP)
under 6 yrs.	ask a doctor
6 to under 12	1-2 TSP

_____ or as directed by a doctor

TSP = teaspoon

Keep out of reach of children.

Overdose warning

Taking more than the recommended dose (overdose) may cause liver damage. In the case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222). Prompt medical attention is critical, even if you do not notice any signs or symptoms.

Other information

- **each teaspoon contains: sodium 7 mg**
- store between 20°-25°C (68°-77°F)
- **tamper evident:** do not use if foil seal over the mouth of the bottle is torn, broken, or missing.

Directions

- may be given every 4 to 6 hours
- do not use more than 6 times in 24 hours
- use only enclosed dosing cup to dose this product. Do not use any other dosing device.

Questions?

877-434-2036

Inactive ingredients

artificial flavor, citric acid anhydrous, CMC sodium, glycerin, polysorbate, propylene glycol, purified water, sodium benzoate, sodium saccharin, sodium citrate dihydrate, sorbitol solution.

Distributed by: AccuDial® Pharmaceutical, Inc. Palm Beach Gardens, FL 33408

PRINCIPAL DISPLAY PANEL - 118 mL Bottle Label

ACCUDIAL®

**Children's
Allergy**

**Diphenhydramine HCl
Oral Solution Antihistamine**

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

***Earth-Friendly
Package!***

For Ages 6 yrs to under 12 yrs

Tamper Evident

Compares to Children's
Benadryl® Allergy

Dye-Free

**BUBBLEGUM
FLAVOR**

NDC 45014-161-04
4 FL. OZ. (118 mL)

▶▶▶ TURN LABEL FOR DRUG FACTS ▶▶▶ TURN LABEL FOR DRUG FACTS ▶▶▶ TURN LABEL FOR DRUG FACTS ▶▶▶

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Palm Beach Gardens, FL 33408

5338-0712 218

Inactive ingredients: artificial flavor, citric acid anhydrous, CMC sodium, glycerin, polysorbate, propylene glycol, purified water, sodium benzoate, sodium saccharin, sodium citrate dihydrate, sorbitol solution.

U.S. Patent Nos. 6,276,533 and 7,172,668.

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6 yrs to under 12 yrs
1-2 TSP



under 6 yrs
Ask a Doctor



5347-0712 218
Go Green Allergy

ALLERGY			
diphenhydramine hydrochloride liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:45014-161
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
Anhydrous Citric Acid (UNII: XF417D3PSL)	
Sodium (UNII: 9NEZ333N27)	
Glycerin (UNII: PDC6A3C0OX)	
Polysorbate 20 (UNII: 7T1F30V5YH)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Water (UNII: 059QF0K00R)	
Sodium Benzoate (UNII: OJ245FE5EU)	
Saccharin Sodium (UNII: SB8ZUX40TY)	
Trisodium Citrate Dihydrate (UNII: B22547B95K)	
Sorbitol (UNII: 506T60A25R)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor	BUBBLE GUM	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:450 14-16 1-04	118 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	02/01/2013	

Labeler - Accudial Pharmaceutical, Inc. (831999201)

Establishment

Name	Address	ID/FEI	Business Operations
Bio-Pharm, Inc.		801652546	ANALYSIS(450 14-16 1) , MANUFACTURE(450 14-16 1) , RELABEL(450 14-16 1) , REPACK(450 14-16 1)

Revised: 2/2013

Accudial Pharmaceutical, Inc.