

DIPHENHYDRAMINE HCL- diphenhydramine hcl liquid
Akron Pharma 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.

Akron Pharma, Inc.

Active ingredient (in each teaspoonful (5 mL))

Diphenhydramine 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 you have

- a breathing problem such as emphysema or chronic bronchitis
- glaucoma
- difficulty in urination due to enlargement of the prostate gland

Ask a doctor or pharmacist before use if you are

taking sedatives or tranquilizers.

When using this product

- avoid alcoholic beverages
- alcohol, sedatives, and tranquilizers may increase drowsiness
- excitability may occur, especially in children
- marked drowsiness may occur
- use caution when driving a motor vehicle or operating machinery

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 (1-800-222-1222) right away.

Directions

- do not take more than 6 doses in 24 hours
- mL = milliliter; FL OZ = fluid ounce
- find right dose on chart below
- take every 4 to 6 hours, or as directed by a doctor

Age	Dose
adults and children 12 years and over	2 - 4 teaspoonsful (25 mg to 50 mg)
children 6 to 11 years	1 - 2 teaspoonsful (12.5 mg to 25 mg)
children 2 to 5 years	do not use unless directed by a doctor
children under 2 years	do not use

Other information

- **each teaspoonful (5 mL) contains:** sodium 5 mg
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- use by expiration date on package

Inactive ingredients

Bubble Gum Flavor, Citric Acid, Purified Water, Sodium Benzoate, Sodium Citrate, Sodium Saccharin, Sorbitol Solution 70% & Sucrose.

Questions or comments?

Please Call 1(877) 225-6999

Manufactured for:

Akron Pharma, Inc,
Fairfield, NJ 07004
Manufactured in U.S.A

Drug Facts (continued)

■ find the right dose on the chart below

Age (yr)	Dose (mL)
children 6 to 11 years	5 mL to 10 mL
children 2 to 5 years	Do not use unless directed by a doctor
children under 2 years	Do not use

Other information

- each 5 mL contains: sodium 8 mg
- store between 20°- 25°C (68°-77°F). Do not refrigerate
- protect from light.

Inactive ingredients

Bubble Gum Flavor, Citric Acid, Purified Water, Sodium Benzoate, Sodium Citrate, Sodium Saccharin, Sorbitol Solution 70% & Sucrose.

Questions or comments?

Call (877) 225-6999 Monday - Friday 9AM - 5PM EST

• This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Benadryl Allergy.

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL AROUND BOTTLE OR UNDER CAP IS BROKEN OR MISSING.

Akron Pharma
Manufactured for
Akron Pharma, Inc.,
Fairfield, NJ - 07004
Rev 09-19
Manufactured in USA

Lot

Exp



Drug Facts (continued)

■ find the right dose on the chart below

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• Compare to the active ingredient in Children's Benadryl Allergy

NDC 71399-0125-4

Dye-Free

Children's Allergy

Antihistamine

Diphenhydramine Hydrochloride 12.5 mg/5 mL Oral Solution Relieves

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

For Ages 6 to 11 Years
Alcohol-Free

Dye-free Bubble Gum Flavored

4 FL OZ (118 mL)

Akron Pharma



• Compare to the active ingredient in Children's Benadryl Allergy

NDC 71399-0125-8

Dye-Free

Children's Allergy

Antihistamine

Diphenhydramine Hydrochloride 12.5 mg/5 mL Oral Solution Relieves

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

For Ages 6 to 11 Years
Alcohol-Free

Dye-free Bubble Gum Flavored

8 FL OZ (236 mL)

Akron Pharma



Drug Facts

Active ingredient (in each 5 mL) Diphenhydramine HCl 12.5 mg Antihistamine

Purpose Antihistamine

Uses

- temporarily relieves these symptoms due to hay fever or other upper respiratory allergies.
- sneezing ■ runny nose ■ Itchy, watery eyes ■ itchy of the nose or throat

Warnings

Do not use

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

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 (1-800-222-1222) right away.

Directions

- do not take more than 6 doses in any 24 hours
- take every 4 to 6 hours, or as directed by a doctor
- measure only with dosing cup provided. Do not use any other dosing device.
- mL=milliliter • keep dosing cup with product

Drug Facts

Active ingredient (in each 5 mL) Diphenhydramine HCl 12.5 mg Antihistamine

Purpose Antihistamine

Uses

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- sneezing ■ runny nose ■ Itchy, watery eyes ■ itchy of the nose or throat

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- mL=milliliter • keep dosing cup with product

Drug Facts		NDC 71399-0125-6	*Compare to the active Ingredient in Children's Benadryl® Allergy	Drug Facts (continued)	
Active ingredient (in each 5 mL)	Purpose			■ find the right dose on the chart below	
Diphenhydramine HCl 12.5 mg.....Antihistamine				Age (yr)	Dose (mL)
Uses ■ temporarily relieves these symptoms due to hay fever or other upper respiratory allergies. ■ sneezing ■ runny nose ■ itchy, watery eyes ■ itchy nose or throat		Dye-free Children's Allergy Antihistamine Diphenhydramine Hydrochloride 12.5 mg/5 mL Oral Solution Relieves: Runny Nose • Sneezing • Itchy, Watery Eyes • Itchy Throat For Ages 6 to 11 years Alcohol-Free Bubble Gum Flavored  Made in USA  16 FL.OZ (473 mL) 	children 6 to 11 years	5 mL to 10 mL	
Warnings Do not use ■ with any other product containing diphenhydramine, even one used on the skin ■ to make a child sleepy			children 2 to 5 years	Do not use unless directed by a doctor	
Ask a doctor before use if the child has ■ a breathing problem such as chronic bronchitis ■ glaucoma ■ a sodium-restricted diet			children under 2 years	Do not use	
Ask a doctor or pharmacist before use if the child is taking sedatives or tranquilizers.			Other Information ■ each 5 mL contains: sodium 8 mg ■ store between 20°- 25°C (68°-77°F). Do not refrigerate ■ protect from light		
When using this product ■ marked drowsiness may occur ■ sedatives and tranquilizers may increase drowsiness ■ excitability may occur, especially in children			Inactive Ingredients Bubble Gum Flavor, Citric Acid, Purified Water, Sodium Benzoate, Sodium Citrate, Sodium Saccharin, Sorbitol Solution 70% & Sucrose.		
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.			Questions or comments? 1-877-225-6999		
Directions ■ do not take more than 6 doses in any 24 hours ■ take every 4 to 6 hours, or as directed by a doctor ■ measure only with dosing cup provided. Do not use any other dosing device. ■ mL = milliliter. ■ keep dosing cup with product			TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL AROUND BOTTLE OR UNDER CAP IS BROKEN OR MISSING. *This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Benadryl® Allergy.		
			Rev.:07/22  Manufactured for: Akron Pharma, Inc. Fairfield, NJ 07004 www.akronpharma.com		
			 N 3 71399 101256 12		

DIPHENHYDRAMINE HCL			
diphenhydramine hcl liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71399-0125
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)			
WATER (UNII: 059QF0KO0R)			
SODIUM BENZOATE (UNII: OJ245FE5EU)			
SODIUM CITRATE (UNII: 1Q73Q2JULR)			
SACCHARIN SODIUM (UNII: SB8ZUX40TY)			
SORBITOL (UNII: 506T60A25R)			
SUCROSE (UNII: C151H8M554)			

Product Characteristics

Color		Score	
Shape		Size	
Flavor	BUBBLE GUM	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71399-0125-4	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/25/2019	
2	NDC:71399-0125-8	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/25/2019	
3	NDC:71399-0125-6	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/01/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	10/25/2019	

Labeler - Akron Pharma Inc. (067878881)

Revised: 2/2023

Akron Pharma Inc.