

**ADWE DYE-FREE CHILDRENS ALLERGY- diphenhydramine hydrochloride syrup
RARITAN PHARMACEUTICALS 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.

Active ingredient (in each 5 mL)

Diphenhydramine HCl USP 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

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

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

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

Attention: use only enclosed dosing cup designed for use with this product. Do not use any other dosing device.

Other information

- **each 5 mL contains:** sodium 3 mg
- store at room temperature)
- protect from sunlight
- see bottom panel for lot number and expiration date
- contains low sodium

Inactive ingredients

anhydrous citric acid, carboxymethylcellulose sodium, flavors, glycerin, potassium citrate, purified water, sodium benzoate, sorbitol, sucralose.

PRINCIPAL DISPLAY PANEL

NDC 68163-710-08

Compare to active ingredient in **Children's Benadryl® Dye-Free***

Children's Allergy Relief

Antihistamine

Diphenhydramine HCl

For Relief Of:

- Runny nose
- sneezing
- itchy, watery eyes
- Itchy Throat or Nose

Natural Cherry Flavor

8 fl oz (236 mL)

Manufactured for:

Adwe Laboratories

1274th 49 Street

Brooklyn, NY 11219

*This product is not manufactured or distributed by Johnson & Johnson, owner of the registered trademark Children's Benadryl® Dye -Free.

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)				
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)				
glycerin (UNII: PDC6A3C0OX)				
POTASSIUM CITRATE (UNII: EE90ONI6FF)				
water (UNII: 059QF0KO0R)				
sodium benzoate (UNII: OJ245FE5EU)				
sorbitol (UNII: 506T60A25R)				
SUCRALOSE (UNII: 96K6UQ3ZD4)				
Product Characteristics				
Color	WHITE (Clear, colorless)	Score		
Shape		Size		
Flavor	CHERRY	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68163-710-08	1 in 1 CARTON	11/22/2021	
1		236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part341	11/22/2021		

Labeler - RARITAN PHARMACEUTICALS INC (127602287)

Revised: 8/2023

RARITAN PHARMACEUTICALS INC