

ADWE DYE-FREE CHILDRENS ALLERGY- diphenhydramine hydrochloride syrup
RARITAN PHARMACEUTICALS INC

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.

1.



ADWE DYE-FREE CHILDRENS ALLERGY

diphenhydramine hydrochloride syrup

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68163-710	
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)				
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 Drug	M010		11/22/2021	

Labeler - RARITAN PHARMACEUTICALS INC (127602287)