

**CHILDRENS ALLERGY- diphenhydramine hydrochloride liquid**  
**AptaPharma Inc.**

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**Drug Facts**

**Active ingredient**  
**(in each 5 mL teaspoon)**

Diphenhydramine HCL 12.5 mg

**Purpose**

Antihistamine

**Uses**

■ Temporarily relieves these symptoms due to hay fever or other respiratory allergies:

- sneezing
- itching of the nose or throat
- runny nose
- itchy watery eyes

■ temporarily relieves these symptoms due to the common cold:

- sneezing
- runny nose

**Warnings**

**Do not use** ■ with any other product containing diphenhydramine, even one used on skin

■ to make a child sleepy

**Ask a doctor before use if the child has**

- glaucoma
- breathing problem such as chronic bronchitis

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

**When using this product**

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

**Keep out of reach of children.**In case of overdose, get medical help or contact a Poison Control Center right away.

**Directions** ■ if needed, take every 4-6 hours ■ do not take more than 6 doses in 24 hours

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Children under 4 years of age:	do not use
Children 4 to under 6 years of age:	do not use unless directed by a doctor
Children 6 to under 12 years of age:	1 to 2 teaspoonfuls (12.5 mg to 25 mg)

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### **Other Information**

■ **Keep carton for full directions for use**

■ each teaspoonful contains: sodium 10 mg

■ store at 20° - 25° C (68° - 77° F)

■ dosage cup provided

### **Inactive ingredients**

Citric acid, D&C Red # 33, FD&C Red # 40, flavor, glycerin, poloxamer 407, purified water, sodium benzoate, sodium chloride, sodium citrate, sucrose

**Questions or comments?** Call weekdays from 9:30 AM to 4:30 PM EST at **1-877-798-5944**.

### **Product Label**

**AP SAFE** NDC 72681-505-24

**COMPARE TO THE  
ACTIVE INGREDIENT IN  
CHILDREN'S BENADRYL®  
ALLERGY LIQUID\***

**Children's  
Allergy  
Relief**

**DIPHENHYDRAMINE HCl  
Liquid  
Antihistamine**

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

• **Alcohol-Free**

4 FL OZ (118 mL) **Cherry Flavor**

**DO NOT USE IF PRINTED SEAL  
UNDER CAP IS TORN OR MISSING**

**2  
1013430  
3/20**

\*This product is not manufactured or

distributed by McNeil PPC, Inc., distributor  
of Benadryl<sup>®</sup> Allergy liquid.

**Manufactured by:**  
**AptaPharma Inc.,**  
**1533 Union Ave.**  
**Pennsauken, NJ 08110**

**AP-BX-03**

**Carton**

MDC 76281-505-24

**DO NOT USE IF PRINTED SEAL UNDER CAP IS TORN OR MISSING**

**Drug Facts**

**Active ingredient (in each 5 mL teaspoonful)** Purpose  
Diphenhydramine HCl 12.5mg.....Antihistamine

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MDC 76281-505-24

**Drug Facts (continued)**

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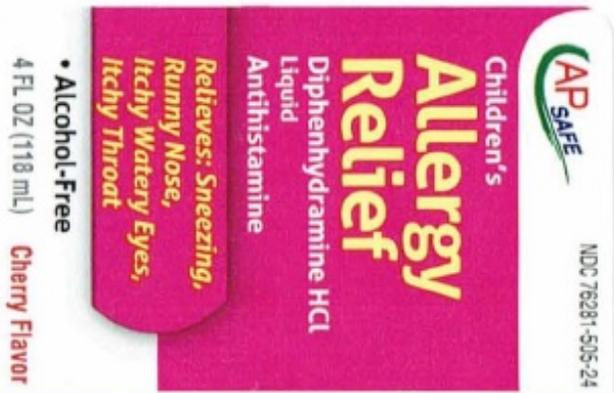
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**Manufactured by:**  
 AptaPharma Inc.,  
 1533 Union Ave.,  
 Pennsauken, NJ 08110

3 76281 50524 5 AP-EX-03

**Bottle**



**DO NOT USE IF PRINTED SEAL UNDER CAP IS TORN OR MISSING**

**Active ingredient (in each 5 mL teaspoonful) Purpose**  
 Diphenhydramine HCl 12.5mg ..... Antihistamine

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Manufactured by: Aptapharma Inc.,  
 1533 Union Ave. Pennsauken, NJ 08110

AP-LR-03

LOT:

EXP:

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**CHILDRENS ALLERGY**

diphenhydramine hydrochloride liquid

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76281-505
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	12.5 mg in 5 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>D&amp;C RED NO. 33</b> (UNII: 9DBA0SBB0L)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLOXAMER 407</b> (UNII: TUF21VW3M2)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	
<b>SUCROSE</b> (UNII: C151H8M554)	

### Product Characteristics

<b>Color</b>	pink	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	CHERRY	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76281-505-24	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/30/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	09/30/2020	

**Labeler** - AptaPharma Inc. (790523323)

**Registrant** - AptaPharma Inc. (790523323)

## Establishment

Name	Address	ID/FEI	Business Operations
AptaPharma Inc.		790523323	manufacture(76281-505)

Revised: 12/2025

AptaPharma Inc.