**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
■ abreathing 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

| | |
|---|---|
| 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) |

***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® Allergy liquid.

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

**AP-BX-03**

**Carton**


NDC 76281-505-24
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
2
1013430
3/20
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
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
■ a 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
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)
Drug Facts (continued)
Other Information
■ Keep carton for full directions for use
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Citric acid, D&C Red # 33, FD&C Red # 40, flavor, glycerin, poloxamer 407, purified water, sodium benzoate, sodium chloride, sodium citrate, sucrose
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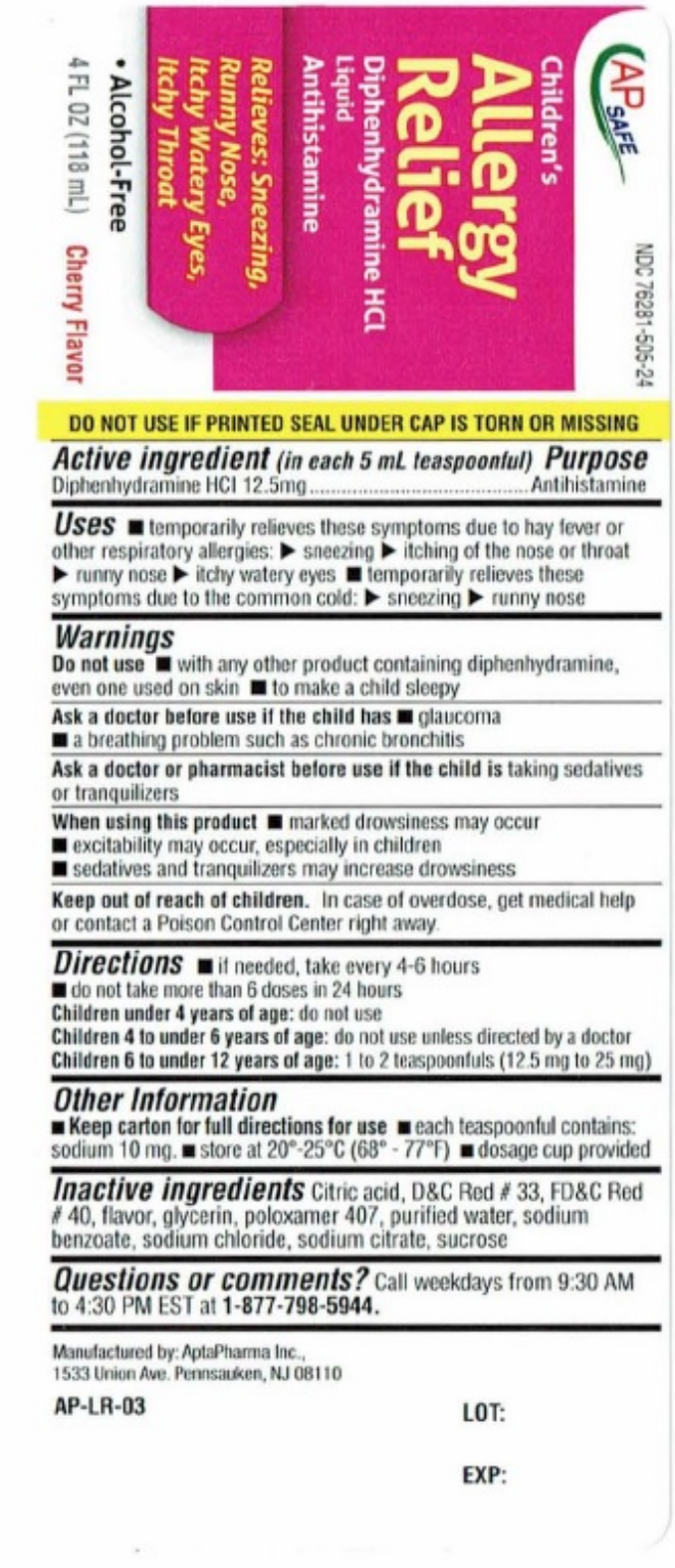
Manufactured by:
AptaPharma Inc.,
1533 Union Ave.
Pennsauken, NJ 08110
3 76281 50524 5
AP-BX-03
AP SAFE
Children's
Allergy Relief
Diphenhydramine HCl
NDC 76281-505-24
COMPARE TO THE ACTIVE INGREDIENT IN CHILDREN'S BENADRYL® ALLERGY LIQUID*
Children's
Allergy Relief
Diphenhydramine HCl
Liquid
Antihistamine
Relieves: Sneezing, Runny Nose, Itchy Watery Eyes, Itchy Throat
• Alcohol-Free
4 FL OZ (118 mL)
Cherry Flavor

**Bottle**

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## CHILDRENS ALLERGY

diphenhydramine hydrochloride liquid

### Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:76281-505 |
| **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 |
|---|---|
| **CITRIC ACID MONOHYDRATE** (UNII: 2968PHW8QP) | |
| **D&C RED NO. 33** (UNII: 9DBA0SBB0L) | |
| **FD&C RED NO. 40** (UNII: WZB9127XOA) | |
| **GLYCERIN** (UNII: PDC6A3C0OX) | |
| **POLOXAMER 407** (UNII: TUF2IVW3M2) | |
| **WATER** (UNII: 059QF0KO0R) | |
| **SODIUM BENZOATE** (UNII: OJ245FE5EU) | |
| **SODIUM CHLORIDE** (UNII: 451W47IQ8X) | |
| **SODIUM CITRATE** (UNII: 1Q73Q2JULR) | |
| **SUCROSE** (UNII: C151H8M554) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | pink | **Score** | |
| **Shape** | | **Size** | |
| **Flavor** | CHERRY | **Imprint Code** | |
| **Contains** | | | |

## 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: 12/2023 AptaPharma Inc.