# DIPHENHYDRAMINE HCL 12.5 MG PER 5 ML- diphenhydramine hcl 12.5 mg per 5 ml solution AARNA USA INC.

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# Active ingredient (in each 5 mL)

Diphenhydramine HCl 12.5 mg

# **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 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
- mL = milliliter
- keep dosing cup with product
- find the right dose on the chart below

Age (yr)

children 6 to 11 years

children 2 to 5 years

children under 2 years

Do not use unless directed by a doctor

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**

anhydrous citric acid, bubble gum favor, purified water, sodium benzoate, sodium citrate, saccharin sodium, sorbitol solution, sucrose.

# Questions or comments?

Please Call 1(877) 225-6999

# Manufactured for:

AARNA USA INC

Leland, NC 28451

<sup>\*</sup>This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Benadryl® Allergy





# 131 mm x 57 mm









#### Drug Facts Active ingredient Purpose (in each 5 mL) Diphenhydramine HCI 12.5 mg..... Antihistamine

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

# Warnings

- 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

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#### 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 (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

anhydrous citric acid, bubble gum flavor, purified water, sodium benzoate, sodium citrate, saccharin sodium, sorbitol

Questions or comments? Call 1-877-225-6999

#### TAMPER EVIDENT: DO NOT USE IF SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

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# 155 mm x 101 mm

# **Drug Facts** Active ingredient (in each 5 mL)

Diphenhydramine HCI 12.5 mg......Antihistamine

Purpose

Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies.

■ sneezing ■ runny nose ■ Itchy, watery eyes ■ itchy nose or throat

#### Warnings

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with any other product containing diphenhydramine, even one used on the skin

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NDC 82568-0016-06 DYE-FREE Children's ALLERGY RELIEF

Diphenhydramine HCL 12.5 mg/5 ml Oral Solution **Antihistamine** 



16 FL.OZ (473 mL)

# Drug Facts (continued)

■ find the right dose on the chart below

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children 2 to 5 years	Do not use unless directed by a doctor	
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#### 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

anhydrous citric acid, bubble gum flavor, purified water, sodium benzoate, sodium citrate, saccharin sodium, sorbitol solution, sucrose.

Questions or comments? 1-877-225-6999

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# **DIPHENHYDRAMINE HCL 12.5 MG PER 5 ML**

diphenhydramine hcl 12.5 mg per 5 ml solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82568-0016
Route of Administration	ORAL		

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

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
SODIUM BENZOATE (UNII: OJ245FE5EU)			
SORBITOL SOLUTION (UNII: 8KW3E207O2)			
SODIUM SACCHARIN (UNII: SB8ZUX40TY)			
SODIUM CITRATE (UNII: 1Q73Q2JULR)			
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)			
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:82568- 0016-4	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/14/2025	
2	NDC:82568- 0016-8	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/14/2025	
3	NDC:82568- 0016-6	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/14/2025	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	04/14/2025	

# **Labeler -** AARNA USA INC. (118515992)

Revised: 4/2025 AARNA USA INC.