

**PHYSICIANS CARE ALLERGY ANTIHISTAMINE- diphenhydramine hydrochloride tablet, film coated**

**Acme United Corporation**

*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.*

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**Physicians Care Allergy**

**Active Ingredients (in each tablet)**

Diphenhydramine Hydrochloride 25 mg

**Purpose**

Antihistamine

**Uses**

**temporarily relieves these symptoms due to hay fever or other respiratory allergies**

- **runny nose**
- **sneezing**
- **itching nose or throat**
- **itchy-watery eyes**

**temporarily relieves these symptoms due to the common cold**

- **runny nose**
- **sneezing**

**Warnings**

**Do Not Use**

- to make a child sleepy
- with any other product containing diphenhydramine, even one that is used on the skin.

**Ask a doctor before use if you have**

- a breathing problem such as emphysema or chronic bronchitis
- difficulty in urination due to enlargement of the prostate gland
- glaucoma

**Ask a doctor or pharmacist before use if you are**

- taking sedatives or tranquilizers

**When using this product**

- \* marked drowsiness may occur and avoid alcoholic beverages
- \* alcohol, sedatives and tranquilizers may increase the drowsiness effect
- \* use caution when driving a motor vehicle or operating machinery
- \* excitability may occur, especially in children

**If pregnant or breast feeding, ask a health professional**

before use

**Keep out of the reach of children.**

In case of overdose, contact a physician or poison control center immediately.

## Directions

Do not use more than directed

## Adults and children: (12 years and older)

Take 1 to 2 caplets every 4 to 6 hours as needed. Do not take more than 12 caplets in 24 hours, or as directed by a doctor.

## Children under 12 years:

Do not give to children under 12 years of age.

## Other information

- each caplet may contain: calcium 25mg
- store at room temperature 59°-86°F (15°-30°C)
- protect from light
- use by expiration date on packet
- tamper-evident sealed packets
- do not use any opened or torn packets

## Inactive ingredients

carnauba wax\*, colloidal silicon dioxide, croscarmellose sodium, D&C red #27, dicalcium phosphate, hypromellose, lactose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80\*, titanium dioxide

\*may contain.

## Questions?

1-800-835-2263

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**Physicians CARE** 90036

**ALLERGY** Antihistamine

THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN.

COATED CAPLET

Tamper-Evident Packets of 1 Tablet  
Do not use if packet is open or torn.

Diphenhydramine Hydrochloride 25 mg  
50 Caplets (50 Packets, 1 caplet each)

**Physicians CARE** 90036

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Diphenhydramine Hydrochloride 25 mg  
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**Drug Facts**

**Active ingredient (in each tablet)** Diphenhydramine Hydrochloride 25 mg

**Purpose** Antihistamine

**Uses**  
temporarily relieves these symptoms due to hay fever or other respiratory allergies  
• runny nose  
• sneezing  
• itchy nose or throat  
• itchy watery eyes

temporarily relieves these symptoms due to the common cold  
• runny nose  
• sneezing

**Warnings**  
Do not use  
• to make a child sleepy  
• with any other products containing diphenhydramine, even one that is used on skin.

**Ask a doctor before use if you have**  
• a breathing problem such as emphysema or chronic bronchitis  
• difficulty in urination due to enlargement of the prostate gland  
• glaucoma

**Ask a doctor or pharmacist before use if you are**  
• taking sedatives or tranquilizers

**When using this product**  
• marked drowsiness may occur if used alcohol beverages,  
alcohol, sedatives and tranquilizers may increase the drowsiness effect  
• use caution when driving a motor vehicle or operating machinery  
• reactively may occur, especially in children

**Drug Facts (continued)**

If pregnant or breast feeding, ask a health professional before use.

Keep out of the reach of children.  
In case of overdose, contact a physician or poison control center immediately.

**Directions**  
Do not use more than directed.

**Adults and children (12 years and older)** Take 1 to 2 caplets every 4 to 6 hours as needed. Do not take more than 12 caplets in 24 hours, or as directed by a doctor.

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**Inactive ingredients**  
croscarmellose sodium, D&C red #27, dicalcium phosphate, hypromellose, lactose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80\*, titanium dioxide  
\*may contain

**Questions?** 1-800-835-2263

Contact Us 1-800-835-2263 www.FirstAidOnly.com

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Mylan Pharmaceuticals, Inc.  
Allentown, PA 18106  
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BANDUNG, CN



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## PHYSICIANS CARE ALLERGY ANTIHISTAMINE

diphenhydramine hydrochloride tablet, film coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0924-0056(NDC:47682-167)
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

### Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
POLYETHYLENE GLYCOL 2000 (UNII: HAF0412YIT)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
HYPROMELLOSE 2208 (100 MPA.S) (UNII: B1QE5P712K)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	

### Product Characteristics

<b>Color</b>	pink (Pink)	<b>Score</b>	no score
<b>Shape</b>	OVAL (Oval)	<b>Size</b>	11mm
<b>Flavor</b>		<b>Imprint Code</b>	048;D
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0924-0056-01	50 in 1 CARTON	11/01/2017	
1		1 in 1 PACKET; 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	11/01/2017	

## PHYSICIANS CARE ALLERGY ANTIHISTAMINE

diphenhydramine hydrochloride tablet, film coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0924-0036(NDC:47682-184)
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

### Inactive Ingredients

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CARNAUBA WAX (UNII: R12CBM0EIZ)	
POLYETHYLENE GLYCOL 2000 (UNII: HAF0412YIT)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
HYPROMELLOSE 2208 (100 MPA.S) (UNII: B1QE5P712K)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	

Product Characteristics				
Color	pink (Pink)	Score	no score	
Shape	OVAL (Oval)	Size	11mm	
Flavor		Imprint Code	061;T	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0924-0036-01	50 in 1 CARTON	11/01/2017	
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Marketing Information				
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OTC monograph final	part341	11/01/2017		

**Labeler** - Acme United Corporation (001180207)

### Establishment

Name	Address	ID/FEI	Business Operations
Acme United Corporation		045924339	relabel(0924-0056, 0924-0036) , repack(0924-0056, 0924-0036)

### Establishment

Name	Address	ID/FEI	Business Operations
Acme United Corporation		080119599	relabel(0924-0056, 0924-0036) , repack(0924-0056, 0924-0036)

Revised: 11/2017

Acme United Corporation