

PHYSICIANS CARE ALLERGY ANTIHISTAMINE- diphenhydramine hydrochloride tablet, film coated
Acme United Corporation

PhysiciansCare 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 ALLERGY ANTIHISTAMINE

diphenhydramine hydrochloride tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0924-0056(NDC:47682-167)
Route of Administration	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)	
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	048;D
Contains			

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 Drug	M012	11/01/2017	

Labeler - Acme United Corporation (001180207)

Establishment

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

Establishment

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