

**DIPHENHYDRAMINE HYDROCHLORIDE- diphenhydramine hydrochloride capsule**  
**Richmond Pharmaceuticals Inc.**

*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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**Diphenhydramine HCl Capsules, USP**

**Drug Facts**

**Active ingredient**

**(in each capsule)**

Diphenhydramine HCl 25 mg

**Purpose**

Antihistamine

**Uses**

temporarily relieves these symptoms of hay fever or other upper respiratory allergies:

- runny nose
- sneezing
- itchy nose or throat
- itchy, watery eyes

**Warnings**

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

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

- glaucoma
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis

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

taking sedatives or tranquilizers

**When using this product**

- you may get very drowsy
- avoid alcoholic drinks
- alcohol, sedatives & tranquilizers may increase drowsiness
- be careful 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 reach of children.**

In case of overdose, get medical help or contact a Poison Control Center right away.

**Directions**

- **adults and children 12 years and over:** take 1 to 2 capsules every 4 to 6 hours; not more than 6 doses in 24 hours
- **children under 12 years:** ask a doctor

Other information

- store at 15-30°C(59-86°F)
- protect from moisture

**Inactive ingredients**

benzyl alcohol, butylparaben, D&C red #28, edible black ink, FD&C blue #1, FD&C red #40, gelatin, lactose, magnesium stearate, methylparaben, polysorbate 80, propylparaben, sodium lauryl sulfate

**Questions or comments?**

call **804-270-4498**, 8:30 am - 4:30 pm ET, Monday – Friday

**TAMPER EVIDENT: DO NOT USE IF BLISTER PACK IS TORN OR DAMAGED**

\*Richmond Pharmaceuticals, Inc. is not affiliated with the owner of the trademark BENADRYL® Allergy.

Distributed by: Richmond Pharmaceuticals Inc., Richmond, VA 23233 Made in USA

RI1010

**Principle Display Panel**

Richmond Pharmaceuticals, Inc.

\*Compare to active ingredient in BENADRYL® Allergy

Diphenhydramine HCl Capsules, USP

25 mg

50 mg

ANTIHISTAMINE

100 CAPSULES (10 x 10)

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

Richmond Pharmaceuticals, Inc.  
 NDC 54738-115-13  
 \*Compare to active ingredient in BENADRYL® Allergy

**Diphenhydramine HCl Capsules, USP**  
**25 mg**

**ANTIHISTAMINE**  
 100 CAPSULES (10 x 10)

<b>Drug Facts</b>
<b>Active ingredient (in each capsule)</b> Diphenhydramine HCl 25 mg ..... Antihistamine
<b>Uses</b> temporarily relieves these symptoms of hay fever or other upper respiratory allergies: ■ runny nose ■ sneezing ■ itchy nose or throat ■ itchy, watery eyes
<b>Warnings</b> Do not use with any other product containing diphenhydramine, even one used on skin.
<b>Ask a doctor before use if you have</b> ■ glaucoma ■ trouble urinating due to an enlarged prostate gland ■ a breathing problem such as emphysema or chronic bronchitis
<b>Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers</b>
<b>When using this product</b> ■ you may get very drowsy ■ avoid alcoholic drinks ■ alcohol, sedatives & tranquilizers may increase drowsiness ■ be careful when driving a motor vehicle or operating machinery ■ excitability may occur, especially in children
<b>If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away.
<b>Directions</b> ■ adults and children 12 years and over: take 1 to 2 capsules every 4 to 6 hours; not more than 6 doses in 24 hours ■ children under 12 years: ask a doctor
<b>Other information</b> ■ store at 15-30°C (59-86°F) ■ protect from moisture
<b>Inactive ingredients</b> benzyl alcohol, butylparaben, D&C red #28, edible black ink, FD&C blue #1, FD&C red #40, gelatin, lactose, magnesium stearate, methylparaben, polysorbate 80, propylparaben, sodium lauryl sulfate
<b>Questions or comments?</b> call 804-270-4498, 8:30 am - 4:30 pm ET, Monday - Friday

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**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

Richmond Pharmaceuticals, Inc.  
 NDC 54738-116-13  
 \*Compare to active ingredient in BENADRYL® Allergy

**Diphenhydramine HCl Capsules, USP**  
**50 mg**

**ANTIHISTAMINE**  
 100 CAPSULES (10 x 10)

<b>Drug Facts</b>
<b>Active ingredient (in each capsule)</b> Diphenhydramine HCl 50 mg ..... Antihistamine
<b>Uses</b> temporarily relieves these symptoms of hay fever or other upper respiratory allergies: ■ runny nose ■ sneezing ■ itchy nose or throat ■ itchy, watery eyes
<b>Warnings</b> Do not use with any other product containing diphenhydramine, even one used on skin.
<b>Ask a doctor before use if you have</b> ■ glaucoma ■ trouble urinating due to an enlarged prostate gland ■ a breathing problem such as emphysema or chronic bronchitis
<b>Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers</b>
<b>When using this product</b> ■ you may get very drowsy ■ avoid alcoholic drinks ■ alcohol, sedatives & tranquilizers may increase drowsiness ■ be careful when driving a motor vehicle or operating machinery ■ excitability may occur, especially in children
<b>If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away.
<b>Directions</b> ■ adults and children 12 years and over: take 1 capsule every 4 to 6 hours; not more than 6 doses in 24 hours ■ children under 12 years: ask a doctor
<b>Other information</b> ■ store at 15-30°C (59-86°F) ■ protect from moisture
<b>Inactive ingredients</b> benzyl alcohol, butylparaben, D&C red #28, edible black ink, FD&C blue #1, FD&C red #40, gelatin, lactose, magnesium stearate, methylparaben, polysorbate 80, propylparaben, sodium lauryl sulfate
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**DIPHENHYDRAMINE HYDROCHLORIDE**

diphenhydramine hydrochloride capsule

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:54738-115
<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
BENZYL ALCOHOL (UNII: LKG8494WBH)	
BUTYLPARABEN (UNII: 3QP1IU3FV8)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
LACTOSE (UNII: J2B2A4N98G)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	

## Product Characteristics

Color	pink (pink, natural)	Score	no score
Shape	CAPSULE	Size	14mm
Flavor		Imprint Code	AP;20
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54738-115-13	100 in 1 BOTTLE; Type 0: Not a Combination Product	02/15/2000	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	02/15/2000	

## DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride capsule

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54738-116
Route of Administration	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	50 mg

## Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
BUTYLPARABEN (UNII: 3QP1IU3FV8)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
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LACTOSE (UNII: J2B2A4N98G)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	

## Product Characteristics

Color	pink (pink, pink)	Score	no score
Shape	CAPSULE	Size	14mm
Flavor		Imprint Code	AP;21
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54738-116-13	100 in 1 BOTTLE; Type 0: Not a Combination Product	02/15/2000	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	02/15/2000	

**Labeler** - Richmond Pharmaceuticals Inc. (043569607)

**Registrant** - Advance Pharmaceutical Inc. (078301063)

## Establishment

Name	Address	ID/FEI	Business Operations
Advance Pharmaceutical Inc.		078301063	manufacture(54738-115, 54738-116)