

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

DIPHENHYDRAMINE HYDROCHLORIDE CAPSULES, USP 25mg

**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
- itchy nose or throat
- sneezing
- 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 4-6 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
- **For 1000 Count: THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN**

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 laurel sulfate

Questions or Comments

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP OR BAND AROUND ANY CAPSULE IS MISSING OR DAMAGED

call 804-270-4498, 8.30 am-4.30 pm ET, Monday - Friday

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

DIPHENHYDRAMINE HYDROCHLORIDE CAPSULE, USP 25 MG -

ANTIHISTAMINE

NDC: 54738-115-24

- 24 COUNT

NDC: 54738-115-01- 100 COUNT

NDC 54738-115-01 *Compare to active ingredient in BENADRYL® Allergy Diphenhydramine HCl Capsules, USP 25 mg TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP OR BAND AROUND ANY CAPSULE IS MISSING OR DAMAGED ANTIHISTAMINE 100 CAPSULES Richmond Pharmaceuticals, Inc.		Drug Facts Active ingredient (in each capsule) Diphenhydramine HCl 25 mgAntihistamine Purpose 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 *Richmond Pharmaceuticals, Inc. is not affiliated with the owner of the trademark BENADRYL® Allergy. Distributed by: Richmond Pharmaceuticals, Inc., Richmond, VA 23223, USA	0 54738 11501 7 LR1114 Lot No.: Exp. Date:
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NDC: 54738-115-03- 1000 COUNT(THIS PACKAGE FOR HOUSEHOLDS

WITHOUT YOUNG CHILDREN)**DIPHENHYDRAMINE HYDROCHLORIDE**

diphenhydramine hydrochloride capsule

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54738-115
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
BENZYL ALCOHOL (UNII: LKG8494WBH)	
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
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	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:54738-115-24	24 in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2015	
2	NDC:54738-115-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2015	
3	NDC:54738-115-03	1000 in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	05/01/2015	

Labeler - Richmond Pharmaceuticals, Inc. (043569607)

Registrant - Advance Pharmaceutical Inc. (078301063)

Establishment

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

Revised: 12/2024

Richmond Pharmaceuticals, Inc.