DIPHENHYDRAMINE HYDROCHLORIDE- diphenhydramine hydrochloride capsule
Advance Pharmaceutical 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.

DIPHENHYDRAMINE HYDROCHLORIDE CAPSULES, USP 50mg

Active Ingredient

(in each capsule)

Diphenhydramine HCl 50 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 capsule 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 bule #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

Manufactured by: Advance Pharmaceutical Inc. Holtsville, NY 11742

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 17714-021-01

*Compare to active ingredient in BENADRYL® Allergy

Diphenhydramine HCl Capsules, USP 50 mg

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

ANTIHISTAMINE

100 CAPSULES

Advance Pharmaceutical Inc.

Drug Facts

Active ingredient (in each capsule)	Purpose
Diphenhydramine HCl 50 mg	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

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- glaucoma
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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 capsule 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 **631-981-4600**
8:30 am - 4:30 pm ET, Monday - Friday

***Advance Pharmaceutical Inc.** is not affiliated with the owner of the trademark BENADRYL® Allergy.

Manufactured by: Advance Pharmaceutical Inc., Holtsville, NY 11742

0 17714 02101 6 LA1212

Lot No.:

Exp. Date:

Advance Pharmaceutical Inc.

NDC 17714-021-10

*Compare to active ingredient in BENADRYL® Allergy

Diphenhydramine HCl Capsules, USP 50 mg

ANTIHISTAMINE

1000 CAPSULES

Drug Facts

Active ingredient (in each capsule) — **Purpose**

Diphenhydramine HCl 50 mg ..... 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 and 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 ■ take every 4-6 hours ■ do not take more than 6 doses in 24 hours

adults & children 12 years & over	1 capsule
children under 12 years	ask a doctor

Other information
■ store at 15°-30°C (59°-86°F) ■ protect from moisture
■ This is a bulk package. Dispense contents in a tight, light-resistant container with a child-resistant closure as defined in the USP

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 **631-981-4600**, 8:30 am - 4:30 pm ET, Monday - Friday

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

THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN

*Advance Pharmaceutical, Inc. is not affiliated with the owner of the trademark BENADRYL® Allergy.

Manufactured by: Advance Pharmaceutical, Inc.
Holtsville, NY 11742

0 17714-02110 8

LA1212

Lot No.:

Exp. Date:

DIPHENHYDRAMINE HYDROCHLORIDE CAPSULE, USP 50 MG

ANTIHISTAMINE

NDC: 17714-021-01 – 100 COUNT

NDC: 17714-021-10 – 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:17714-021
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: 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;021
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:17714-021-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	10/05/1989	

2	NDC:17714-021-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	10/05/1989	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	10/05/1989	

Labeler - Advance Pharmaceutical Inc. (078301063)

Registrant - Advance Pharmaceutical Inc. (078301063)

Establishment

Name	Address	ID/FEI	Business Operations
Advance Pharmaceutical Inc.		078301063	manufacture(17714-021)

Revised: 12/2017 Advance Pharmaceutical Inc.