DIPHENHYDRAMINE HYDROCHLORIDE- diphenhydramine hydrochloride tablet
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 HCl 25mg, USP

Active Ingredient

(in each tablet)

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

- take every 4-6 hours
- do not take more than 6 doses in 24 hours
- **adults and children 12 years and over :** 1-2 tablets

- **children under 12 years:** ask a doctor

Other Information

- **each tablet contains:** calcium 45 mg
- store at 15-30 °C (59-86 °F)
- protect from moisture

Inactive Ingredients

croscarmellose sodium, D&C red# 27, dicalcium phosphate, magnesium stearate, microcrystalline cellulose, opadry clear, titanium dioxide

Questions or Comments

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BOKEN OR MISSING

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

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Advance Pharmaceutical Inc.

100 MINI TABLETS

EASY TO SWALLOW

ANTIHISTAMINE

Relieves
- *Runny Nose*
- *Sneezing*
- *Itchy Nose or Throat*
- *Itchy, Watery Eyes*

DIPHENHYDRAMINE HCl 25 mg., USP

*Compare to active ingredient in BENADRYL® ALLERGY

NDC 17714-135-01

Drug Facts

Active ingredient (in each tablet)	Purpose
Diphenhydramine HCl 25 mg	Antihistamine

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Drug Facts continued on back of label

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

*Advance Pharmaceutical Inc., Holtsville, NY 11742 is not affiliated with the owner of the trademark BENADRYL® ALLERGY

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

Lot No.:

Exp. Date:

PEEL HERE FOR MORE DRUG FACTS

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LA0513

DIPHENHYDRAMINE HYDROCHLORIDE TABLETx`, USP 25 MG

ANTIHISTAMINE

NDC: 17714-135-01 – 100 MINI TABLETS

DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:17714-135
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
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	pink	**Score**	no score
Shape	CAPSULE	**Size**	11mm
Flavor		**Imprint Code**	AP;135
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17714-135-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	09/26/2006	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	09/26/2006	

Labeler - Advance Pharmaceutical Inc. (078301063)

Registrant - Advance Pharmaceutical Inc. (078301063)

Establishment

Name	Address	ID/FEI	Business Operations
Advance Pharmaceutical Inc.		078301063	manufacture(17714-135)

Revised: 12/2017 Advance Pharmaceutical Inc.