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 HYDROCHLORIDE TABLETS, USP 50mg

Active Ingredient

(in each TABLET)

Diphenhydramine HCl 50 mg

Purpose

Sleep Aid

Uses

relieves occasional sleeplessness

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 tablet at bedtime
- **children under 12 years:** ask a doctor

Other Information

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

Inactive Ingredients

Croscarmellose sodium, dicalcium phosphate, FD&C blue# 1(Al-lake), Magnesium stearate, microcrystalline cellulose.

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

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

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

DIPHENHYDRAMINE HYDROCHLORIDE Tablet, USP 50 MG

ANTIHISTAMINE

NDC: 17714-023-50 – 50 COUNT

DIPHENHYDRAMINE HYDROCHLORIDE diphenhydramine hydrochloride tablet	
Product Information	

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:17714-023
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
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	blue (light)	**Score**	no score
Shape	ROUND	**Size**	11mm
Flavor		**Imprint Code**	AP;023
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17714-023-50	50 in 1 BOTTLE; Type 0: Not a Combination Product	09/01/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	09/01/2012	

Labeler - Advance Pharmaceutical Inc. (078301063)

Registrant - Advance Pharmaceutical Inc. (078301063)

Establishment

Name	Address	ID/FEI	Business Operations
Advance Pharmaceutical Inc.		078301063	manufacture(17714-023)