

**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.*

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**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**

**ANTI-HISTAMINE**

**NDC: 17714-023-50 – 50 COUNT**

NDC 17714-023-50  
\*Compare to active ingredient in COMPOZ<sup>®</sup>

**Nighttime Sleep Aid**  
**DIPHENHYDRAMINE HCl**  
**50 mg.**  
**Adult Strength**  
**50 BLUE TABLETS**

 Advance  
Pharmaceutical Inc.

**Drug Facts**

**Active ingredient (in each tablet)**  
Diphenhydramine HCl 50 mg ..... Sleep Aid

**Purpose**  
Use 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**

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

**Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers**

**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 COMPOZ<sup>®</sup>

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

Lot No.:  
Exp. Date:  
PEEL HERE FOR MORE DRUG FACTS

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**Drug Facts (continued)**

**When using this product avoid alcoholic drinks**

**Stop use and ask a doctor if**

- sleeplessness lasts more than 2 weeks.
- insomnia may be a symptom of a serious underlying medical illness.

**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 & children 12 years and over: one tablet at bedtime
- children under 12 years: ask a doctor

**Other information**

- each tablet contains: calcium 86 mg
- store at room temperature 15°-30°C (59°-86°F)

**Inactive ingredients**  
croscarmellose sodium, dicalcium phosphate, FD&C blue #1 alum. lake, magnesium stearate, microcrystalline cellulose

**Questions or comments?**  
call 631-981-4600, 8:30 am to 4:30 pm ET, Monday - Friday

## DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride tablet

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:17714-023	
<b>Route of Administration</b>	ORAL			
<b>Active Ingredient/Active Moiety</b>				
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>	
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)		DIPHENHYDRAMINE HYDROCHLORIDE	50 mg	
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>			<b>Strength</b>	
CROSCARMELOSE 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)				
<b>Product Characteristics</b>				
<b>Color</b>	blue (light)	<b>Score</b>	no score	
<b>Shape</b>	ROUND	<b>Size</b>	11mm	
<b>Flavor</b>		<b>Imprint Code</b>	AP;023	
<b>Contains</b>				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:17714-023-50	50 in 1 BOTTLE; Type 0: Not a Combination Product	09/01/2012	
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
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)

