

**DIPHENHYDRAMINE HYDROCHLORIDE- diphenhydramine  
hydrochloride capsule, liquid filled  
Prodose, Inc.**

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**Diphenhydramine Hydrochloride Capsules USP 50 mg (Dye-free)**

***Active ingredient  
(in each softgel)***

Diphenhydramine Hydrochloride USP 50 mg

***Purpose***

Nighttime sleep-aid

***Uses***

- for relief of occasional sleeplessness

***Warnings***

**Do not use**

- for children under 12 years of age
- with any other product containing diphenhydramine, even one used on skin

**Ask a doctor before use if you have**

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

**Ask a doctor or pharmacist before use if you are**

taking sedatives or tranquilizers

**When using this product**

avoid alcoholic drinks

**Stop use and ask a doctor if**

sleeplessness persist continuously for 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 and children 12 years of age and over: 1 softgel (50 mg) at bedtime if needed, or as directed by a doctor

**Inactive ingredients**

gelatin, glycerin, polyethylene glycol 400, polyethylene glycol 600, propylene glycol, purified water, sorbitol sorbitan solution.

**Bulk Package Label**

<b>Diphenhydramine Hydrochloride Capsules USP 50mg (Dye Free)</b>		<b>IMPRINT</b>
<u>Each Soft Gelatin Capsule Contains:</u> (Diphenhydramine Hydrochloride USP 50mg)		
BATCH NO. :	NDC NO : 68210-5057-1	
GROSS WT :	MFG. DATE :	
NET WT :	EXP DATE :	
QUANTITY :	SHIPPER NO :	
<b>WARNING</b> KEEP OUT OF REACH OF CHILDREN		
STORE BETWEEN 20° - 25°C (68° to 77°F). AVOID HIGH HUMIDITY AND EXCESSIVE HEAT. PROTECT FROM LIGHT.		
THIS IS BULK SHIPMENT INTENDED FOR FURTHER PROCESSING ONLY. CONTENTS SHOULD BE APPROVED, REPACKED IMMEDIATELY AND LABELED IN STRICT CONFORMANCE WITH THE F.D. & C ACT AND REGULATIONS.		
<b>MANUFACTURED FOR:</b>  <b>PRODOSE INC.,</b> 2004 ORVILLE DRIVE NORTH RONKONKOMA, NEW YORK (NY) 11779, UNITED STATES (USA) LABELLER CODE : 68210		
<b>CAUTION: "FOR MANUFACTURING, PROCESSING OR REPACKAGING"</b>		

**DIPHENHYDRAMINE HYDROCHLORIDE**

diphenhydramine hydrochloride capsule, liquid filled

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68210-5057
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	50 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>POLYETHYLENE GLYCOL 600</b> (UNII: NL4J9F21N9)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	

## Product Characteristics

<b>Color</b>	white (Clear transparent)	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	13mm
<b>Flavor</b>		<b>Imprint Code</b>	02
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-5057-1	2 in 1 BOX	07/30/2025	
1		3000 in 1 POUCH; Type 0: Not a Combination Product		

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC Monograph Drug	M010	07/30/2025	

**Labeler** - Prodose, Inc. (119371190)

