

**DIPHENHYDRAMINE HYDROCHLORIDE- diphenhydramine hydrochloride tablet, coated**  
**Time-Cap Labs, 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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**329R DIP HCL**

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Active Ingredient  
(in each caplet)

Diphenhydramine Hcl 25 mg

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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

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

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Do not use  
to make a child sleepy; with any other product containing diphenhydramine, even one used on skin.

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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.

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Warnings

Do not use to make a child sleepy; Do not use with any other product containing diphenhydramine even one used on skin.

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If pregnant or breast-feeding ask a health professional before use.

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Uses: temporarily relieves these symptoms due to hay fever or other upper respiratory allergies  
runny nose; itchy water eyes sneezing; itchy nose or throat  
Temporarily relieves these symptoms due to the common cold: runny nose; sneezing

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When using this product

Avoid alcoholic drinks

marked drowsiness may occur

Alcohol, sedatives, and tranquilizers may increase drowsiness

Excitability may occur, especially in children

Be careful when driving a motor vehicle or operating machinery

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Directions:

Take every 4 to 6 hours

Do not take more than 6 doses in 24 hours

Adults and children 12 years of age and over - 1 to 2 caplets

Children 6 to under 12 years of age - 1 caplet

Children under 6 years of age - Do not use this product in children under 6 years of age

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Carnauba Wax, Colloidal Silicon Dioxide, Croscarmellose Sodium, Dibasic Calcium Phosphate Dihydrate, Hypromellose, Magnesium Stearate, Microcrystalline Cellulose, Polyethylene Glycol, Polysorbate 80, Titanium Dioxide

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Uses: Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies; runny nose, itchy watery eyes; sneezing; itchy nose or throat

Temporarily relieves these symptoms due to the common cold: runny nose; sneezing

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**DIPHENHYDRAMINE HYDROCHLORIDE**

diphenhydramine hydrochloride tablet, coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:49483-329
<b>Route of Administration</b>	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
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	7mm
<b>Flavor</b>		<b>Imprint Code</b>	help
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49483-329-00	100000 in 1 CARTON; Type 0: Not a Combination Product	12/17/2018	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	03/01/2010	

**Labeler** - Time-Cap Labs, Inc (037052099)

**Registrant** - Time-Cap Labs, Inc (037052099)

**Establishment**

Name	Address	ID/FEI	Business Operations
Time-Cap Labs, Inc		037052099	manufacture(49483-329)

Revised: 12/2018

Time-Cap Labs, Inc