# DIPHENHYDRAMINE HCL 25 MG- diphenhydramine hcl tablet Reliable 1 Laboratories LLC

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 HCL 25 mg Caplets

## **Drug Facts**

## Active ingredient (in each caplet)

Diphenhydramine HCL 25 mg

## **Purpose**

**Antihistamine** 

#### Uses

temporarily relieves these symptoms of hay fever or other upper respiratory allergies:

- runny nose
- sneezing
- itchy nose or throat
- itchy, watery eyes

# Warnings

#### Do not use

- with any other product containing diphenhydramine, even one use on skin
- to make a child sleepy

# Ask a doctor before use if you have

- glaucoma
- trouble urinating due to an enlarged prostate gland
- a breating 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

# 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 breat-feeding, ask a health professional before use.

**Keep out of reach of children.** In case of overdose, get medical helo 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 to 2 caplets
children 6 to under 12 years	1 caplet
children under 6 years	do not use

#### Other information

- each caplet contains: calcium 45 mg
- store at room temperature
- protect from moisture

### Inactive ingredients

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

#### Questions or comments?

call **516-341-0666**, 8:30 am - 4:30 pmET, Monday - Friday

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

\*Reliable 1 Laboratories LLC is not affiliated with the owner of the trademark BENADRYL®

Distributed by: Reliable 1 Laboratories LLC

Valley Stream, NY 11580

www.reliable1labs.com

NDC 69618-025-01

Diphenhydramine HCL 25 mg

**ANTIHISTAMINE** 

**100 CAPLETS** 

<sup>\*</sup>Compare to Active Ingredient in BENADRYL® ALLERGY



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#### **DIPHENHYDRAMINE HCL 25 MG**

diphenhydramine hcl tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69618-025
Route of Administration	ORAL		

# Active Ingredient/Active Moiety Ingredient Name Basis of Strength DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M) DIPHENHYDRAMINE HYDROCHLORIDE 25 mg

Inactive Ingredients			
Ingredient Name	Strength		
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)			
<b>D&amp;C RED NO. 27</b> (UNII: 2LRS185U6K)			
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)			
HYPROMELLOSES (UNII: 3NXW29V3WO)			

MAGNESIUM STEARATE (UNII: 70097M6I30)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)	
TITANIUM DIOYIDE (LINII: 15EIYQ\/2IP)	

Product Characteristics			
Color	pink	Score	no score
Shape	OVAL	Size	11mm
Flavor		Imprint Code	AP;135
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:69618- 025-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/01/2015	



Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	11/01/2015	

# Labeler - Reliable 1 Laboratories LLC (079718111)

# Registrant - Reliable 1 Laboratories LLC (079718111)

Revised: 3/2023 Reliable 1 Laboratories LLC