

DIPHENHYDRAMINE HCL 25 MG- diphenhydramine hcl capsule
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.

Diphenhydramine HCL 25 mg Capsules

Active ingredient (in each capsule)

Diphenhydramine HCL 25 mg

Purpose

Antihistamine

Uses

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

- runny nose
- itchy nose or throat
- sneezing
- 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 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 of 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 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

- 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 capsules
children 6 to under 12 years	1 capsule
children under 6 years	do not use

Other information

- store at room temperature
- protect from moisture

Inactive ingredients

benzyl alcohol, butylparaben, D&C red #28, edible black ink, FD&C blue #1, FD&C red #40, gelatin, lactose, magnesium stearate, methylparaben, polysorbate 80, propylparaben, sodium lauryl sulfate

Questions or comments?

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

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP OR BAND AROUND ANY CAPSULE IS BROKEN OR MISSING

Distributed by: **Reliable 1 Laboratories LLC**

Valley Stream, NY 11580

www.reliable1labs.com

Drug Facts

NDC 69618-024-01

Diphenhydramine HCL 25 mg

ANTIHISTAMINE

100 CAPSULES

NDC 69618-024-01



Diphenhydramine HCl
25 mg
ANTIHISTAMINE

100 CAPSULES

Drug Facts

Active ingredient (in each capsule)
Diphenhydramine HCl 25 mg Antihistamine

Purpose
Uses temporarily relieves these symptoms of hay fever or other upper respiratory allergies:
 ■ runny nose ■ itchy nose or throat
 ■ sneezing ■ itchy, watery eyes

Warnings
Do not use ■ with any other product containing diphenhydramine, even one used 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 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

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Manufactured by: Reliable 1 Laboratories LLC
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Rev. 0716



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

Drug Facts (continued)

When using this product
 ■ you may get very drowsy
 ■ avoid alcoholic drinks
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 ■ 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
 ■ take every 4-6 hours
 ■ do not take more than 8 doses in 24 hours

adults and children 12 years and over	1 to 2 capsules
children 6 to under 12 years	1 capsule

children under 6 years **do not use**

Other information
 ■ store at room temperature
 ■ protect from moisture

Inactive ingredients: benzyl alcohol, butylparaben, D&C red #28, edible black ink, FD&C blue #1, FD&C red #40, gelatin, lactose, magnesium stearate, methylparaben, polyborate 80, propylparaben, sodium lauryl sulfate

Questions or comments?
 call 516-941-0888, 8:30 am - 4:30 pm ET, Monday - Friday

DIPHENHYDRAMINE HCL 25 MG

diphenhydramine hcl capsule

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69618-024
Route of Administration	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
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
METHYLPARABEN (UNII: A218C7HI9T)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
GELATIN (UNII: 2G86QN327L)	

POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
LACTOSE (UNII: J2B2A4N98G)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

Product Characteristics

Color	pink (Half pink and half white)	Score	no score
Shape	CAPSULE	Size	14mm
Flavor		Imprint Code	AP;20
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69618-024-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/01/2015	



DIPHENHYDRAMINE 25mg Capsule

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)