

DIPHENHYDRAMINE HYDROCHLORIDE- diphenhydramine hydrochloride tablet
Precision Dose, Inc.

Diphenhydramine Hydrochloride

25 mg Tablets

For Hospital Use Only

Drug Facts

Active ingredient (in each tablet)

Diphenhydramine 25 mg

Purpose

Antihistamine

Uses

- temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
 - runny nose
 - sneezing
 - itchy, watery eyes
 - itching of nose
- temporarily relieves these symptoms due to the common cold:
 - runny nose
 - sneezing

Warnings

Do not use

- to make a child sleepy
- 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

- marked drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and 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 (1-800-222-1222).

Directions

- **Use as directed per healthcare professional.**
- take every 4 to 6 hours, or as directed by a doctor
- do not take more than 6 doses in 24 hours

adults and children 12 years and older	1 to 2 tablets
children 6 to under 12 years	1 tablet
children under 6 years	do not use

Other information

- **each tablet contains:** calcium 20 mg
- store at 20-25°C (68-77°F).
- Avoid high humidity. Protect from light
- small tablet size, easy to swallow

Inactive ingredients

carnauba wax, crospovidone, D&C red no. 27 aluminum lake, dibasic calcium phosphate dihydrate, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, pregelatinized starch, stearic acid, titanium dioxide

Questions or comments?

1-800-397-9228

Gluten Free

How Supplied

They are supplied as follows:

NDC 68094-018-61

Unit Dose Packages of 100 Tablets (10×10) per Carton

Packaged by:

Precision Dose, Inc.

South Beloit, IL 61080

For inquiries call Precision Dose, Inc. at 1-800-397-9228 or email druginfo@precisiondose.com

LI1499
Rev. 10/23

PRINCIPAL DISPLAY PANEL - 25 mg Tablet Blister Pack Carton Label

Precision Dose™

NDC 68094-018-61

Unit Dose

diphenhydrAMINE HCl

25 mg Tablets

100 Tablets

(10x10)

Each tablet contains:

Diphenhydramine Hydrochloride 25 mg

Calcium 20 mg

Gluten Free

USUAL DOSE: SEE ENCLOSED INSERT.

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LC1498

R0

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L11499 Rev. 10/23

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DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68094-018(NDC:0113-0479)
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
carnauba wax (UNII: R12CBM0EIZ)	
crospovidone (120 .MU.M) (UNII: 68401960MK)	
D&C Red No. 27 (UNII: 2LRS185U6K)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
Magnesium Stearate (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
Polysorbate 80 (UNII: 6OZP39ZG8H)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
Titanium dioxide (UNII: 15FIX9V2JP)	
anhydrous dibasic calcium phosphate (UNII: L11K75P92J)	

Product Characteristics

Color	PINK (dark)	Score	no score
Shape	OVAL	Size	10mm
Flavor		Imprint Code	L479;25
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68094-018-61	10 in 1 CARTON	07/15/2019	
1	NDC:68094-018-59	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph drug	M012	07/15/2019	

Labeler - Precision Dose, Inc. (035886746)

Establishment

Name	Address	ID/FEI	Business Operations
Precision Dose, Inc.		035886746	REPACK(68094-018)

Revised: 2/2024

Precision Dose, Inc.