

ANTI-HISTAMINE- diphenhydramine hcl capsule
Gendose Pharmaceuticals, LLC

Active ingredient (in each banded capsule)

Diphenhydramine Hydrochloride 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 the nose or throat
- temporarily relieves these symptoms due to the common cold:
 - runny nose
 - sneezing

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

Ask a doctor or pharmacist before use if you are

taking sedatives or tranquilizers.

When using this product

- drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- use caution 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 accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) immediately.

Directions

- take every 4 to 6 hours or as directed by a doctor
- do not take exceed 6 doses in 24 hours
- adults and children 12 years and older: 1 capsule to 2 capsules
- children 6 to under 12 years: 1 capsule
- children under 6 years: do not use this product in children under 6 years of age

Other information

- store at 20° - 25°C (68°-77°F)

Inactive ingredients

butylparaben, corn starch, D&C Red #28, edible ink, FD&C Blue #1, FD&C Red #40, gelatin, lactose anhydrous, magnesium stearate, methylparaben, polysorbate 80, propylparaben, silicon dioxide

Questions or comments?

Call 1-888-676-7161

Principal Display Panel

The image shows the principal display panel for Diphenhydramine HCl 25 mg Capsules. The panel is rectangular with a white background and a blue border. It contains the following information:

- NDC 77333-227-10**
- Diphenhydramine HCl 25 mg Capsules**
- Antihistamine**
- UD 100 Capsules (10x10)**
- A barcode with the number **(01) 0 03 77333 227 10 8** below it.
- GenDose® Pharmaceuticals**
- NDC 77333-227-10**
- Diphenhydramine HCl 25 mg Capsules**
- Drug Facts**
- Active ingredient (in each banded capsule)** Purpose: Diphenhydramine Hydrochloride 25 mg.....Antihistamine
- Uses**: temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: • runny nose • sneezing • itchy, watery eyes • itching of the nose or throat
temporarily relieves these symptoms due to the common cold:
• runny nose • sneezing
- 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 • a breathing problem such as emphysema or chronic bronchitis • 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** • drowsiness may occur • avoid alcoholic drinks • alcohol, sedatives, and tranquilizers may increase drowsiness • use caution 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 (1-800-222-1222) immediately.
- Directions** • take every 4 to 6 hours, or as directed by a doctor
• do not exceed 6 doses in 24 hours
• adults and children 12 years and older: 1 capsule to 2 capsules
• children 6 to under 12 years: 1 capsule
• children under 6 years: do not use this product in children under 6 years of age
- Other information** • store at 20° - 25°C (68° - 77°F)
- Inactive ingredients** butylparaben, corn starch, D&C Red #28, edible ink, FD&C Blue #1, FD&C Red #40, gelatin, lactose anhydrous, magnesium stearate, methylparaben, polysorbate 80, propylparaben, silicon dioxide
- Questions or comments?** Call 1-888-676-7161

ANTIHISTAMINE

diphenhydramine hcl capsule

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77333-227
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
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
STARCH, CORN (UNII: O8232NY3SJ)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	pink, white (Natural)	Score	no score
Shape	CAPSULE	Size	14mm
Flavor		Imprint Code	44;107
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77333-227-10	100 in 1 BOX	05/15/2026	
1	NDC:77333-227-25	1 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
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OTC Monograph Drug M012

05/15/2026

Labeler - Gendose Pharmaceuticals, LLC (080257510)

Registrant - Gendose Pharmaceuticals, LLC (080257510)

Revised: 5/2026

Gendose Pharmaceuticals, LLC