

ALLERGY RELIEF- diphenhydramine hcl tablet
P & L Development, 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.

DRUG FACTS

Active ingredient (in each tablet)

Diphenhydramine HCL 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

- 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 (1-800-222-1222) right away.

Directions

- 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 over	take 1 to 2 tablets
children 6 to under 12 years	take 1 tablet
children under 6 years	do not use

Other information

- **each tablet contains:** calcium 25 mg
- store between 20-25°C (68-77°F)
- protect from light and moisture

Inactive ingredients

carnauba wax, colloidal silicon dioxide, croscarmellose sodium, D&C Red #27 Aluminum Lake, dibasic calcium phosphate dihydrate, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, titanium dioxide

Questions or comments?

Call **1-877-753-3935** Monday- Friday 9AM- 5PM EST

Principal Display Panel

**Compare to the active ingredient in Benadryl® Allergy Ultratab®

allergy relief

diphenhydramine HCL 25 mg

antihistamine

tablets

**This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Benadryl® Allergy Ultratab®.

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

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Distributed by: **PL Developments**

200 Hicks Street, Westbury, NY 11590

Product Label

Exp. Date:
Lot No.:
PLD-8587B
FC006158



allergy relief

diphenhydramine HCl 25 mg
antihistamine
100 tablets

**Compare to the active ingredient
in Benadryl® Allergy Ultratabs®

Drug Facts

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Drug Facts (continued)

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Actual Size

Distributed by: **PL Developments**
200 Hicks Street, Westbury, NY 11590

ALLERGY RELIEF

diphenhydramine hcl tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59726-766
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)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
CALCIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: O7TSZ97GEP)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	pink	Score	no score
Shape	CAPSULE	Size	11mm
Flavor		Imprint Code	T;061
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59726-766-40	400 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/29/2019	11/29/2024
2	NDC:59726-766-10	1 in 1 BOX	11/29/2019	11/29/2024
2		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part336	11/29/2019	11/29/2024

Labeler - P & L Development, LLC (800014821)

Revised: 3/2023

P & L Development, LLC