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 of 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® Tablets† allergy relief

diphenhydramine HCL 25 mg

antihistamine

for allergy relief:

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

tablets

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

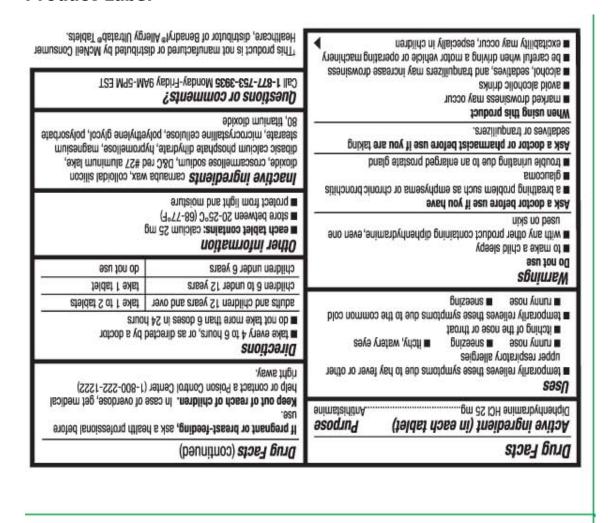
TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Distributed by: **PL Developments**

200 Hicks Street, Westbury, NY 11590

Product Label



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allergy relief

diphenhydramine HCl 25 mg



Compare to the active ingredient in Benadryl® Allergy Ultratab® Tablets†

NDC 59726-866-12

allergy relief

diphenhydramine HCl 25 mg

TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF BLISTER UNI

antihistamine for allergy relief:

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

actual size



12 tablets



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



READYinCASE Allergy Relief

ALLERGY RELIEF

diphenhydramine hcl tablet

Product Information

Product Type HUMAN OTC DRUG **Item Code (Source)** NDC:59726-866

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			

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:59726- 866-40	400 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/31/2019	12/31/2024		
2	NDC:59726- 866-12	12 in 1 CARTON	07/31/2019	12/31/2024		
2		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
OTC monograph final	part336	07/31/2019	12/31/2024

Revised: 3/2023 P & L Development, LLC