

ALLERGY- diphenhydramine hydrochloride tablet

Velocity Pharma 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 25mg, USP

Active Ingredient

(in each tablet)

Diphenhydramine HCl 25 mg

Purpose

Antihistamine

Uses

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

- runny nose
- itching of the nose or throat
- sneezing
- itchy, watery eyes

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

- 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

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. (1-800-222-1222)

Directions

- **adults and children 12 years and over** : take 1-2 tablets every 4 to 6 hours; not more than 6 doses in 24 hours
- **children under 12 years**: ask a doctor

Other Information

- save carton for full directions and warnings
- store at 25°C(77 °F) excursions permitted between 15°-30°C (59°-86°F)
- this product contains 100.75 milligrams of calcium.
- Do not use if imprinted safety seal under cap is broken or missing

Inactive Ingredients

Carnauba Wax, Colloidal silicon dioxide, croscarmellose sodium, D&C red #27 al lake, dibasic calcium phosphate dihydrate, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol (PEG) 400, polysorbate 80, Titanium Dioxide

Questions or Comments

Call 1-855-314-1850

READ AND KEEP CARTON FOR COMPLETE WARNING AND INFORMATION

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



VP CT 077 DG Allergy 100CT Carton

ALLERGY

diphenhydramine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76 168 -121
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)				
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)				
HYPROMELLOSES (UNII: 3NXW29V3WO)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)				
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)				
POLYSORBATE 80 (UNII: 6OZP39ZG8H)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
Product Characteristics				
Color	pink	Score	no score	
Shape	CAPSULE	Size	11mm	
Flavor		Imprint Code	DP	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76168-121-12	100 in 1 BOTTLE	05/14/2018	
1		1 in 1 CARTON; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph final	part341		05/14/2018	

Labeler - Velocity Pharma LLC (962198409)