# ALLERGY- diphenhydramine hydrochloride tablet Velocity Pharma

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.

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#### **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) excusrsions 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 silion 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**

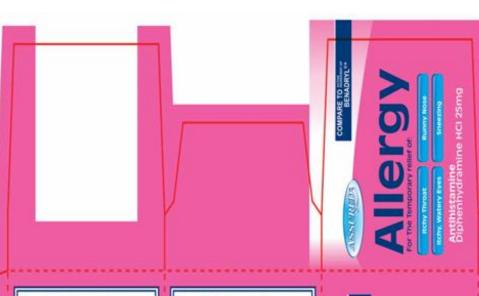
Call 1-855-314-1850

READ AND KEEP CARTON FOR COMPLETE WARNING AND INFORMATION

#### PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



VP CT 077 DG Allergy 100CT Carton



#### Drug Facts (continued)

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#### Questions or comments?

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READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

POSSICIONE

#### **Drug Facts**

Active Ingredient in each tablet Diphenhydramine HCI 25 mg Purpose

**Antihistamine** 

temporarily relieves these symptoms of 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

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ASSALLTC

Distributed By: Greenbrier International, Inc., Chesapeake, VA 23320 MADE IN USA



#### DIPHENHYDRAMINE HYDROCHLORIDE TABLET, USP 25 MG

#### **ANTIHISTAMINE**

NDC:76168-013-07 36TABLETS

NDC:76168-013-12 100 TABLETS

#### **ALLERGY**

diphenhydramine hydrochloride tablet

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Prod	luct	Into	rmation

Product Type HUMAN OTC DRUG Item Code (Source) NDC:76168-013

Route of Administration ORAL

#### Active Ingredient/Active Moietv

Ingredient Name	Basis of Strength	Strength
<b>DIPHENHYDRAMINE HYDRO CHLO RIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE -	DIPHENHYDRAMINE	25 mg
UNII:8GTS82S83M)	HYDROCHLORIDE	20 1116

Ingredient Name

CARNAUBA WAX (UNII: R12CBM0EIZ)

SILICON DIO XIDE (UNII: ETJ7Z6XBU4)

CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)

D&C RED NO. 27 (UNII: 2LRS185U6K)

DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)

HYPRO MELLOSES (UNII: 3NXW29V3WO)

MAGNESIUM STEARATE (UNII: 70097M6130)

CELLULOSE, MICRO CRYSTALLINE (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	EL
Contains			

P	Packaging			
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:76168-013-07	36 in 1 BOTTLE	05/12/2012	
1		1 in 1 CARTON; Type 0: Not a Combination Product		
2	NDC:76168-013-12	100 in 1 BOTTLE	12/15/2016	
2		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	05/12/2012		

# Labeler - Velocity Pharma (962198409)

Revised: 12/2016 Velocity Pharma