## ALLERGY- diphenhydramine hydrochloride tablet Mckesson

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

- 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**

- 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**

- take every 4 to 6 hours
- do not take more than 6 tablets in 24 hours

Age (Yr)	Dose (tablets)
Adults and children 12 years of age and over	Take 1 to 2 tablets
Children 6 to under 12 years of age	Take 1 tablet
Children under 6 years of age	do not use

#### Other Information

- store at 25°C(77 °F) excusrsions permitted between 15°-30°C (59°-86°F)
- protect from light and moisture
- metal content: each tablet contains: Calcium 23mg, Magnesium: 0.2 mg, sodium 0.5 mg

#### **Inactive Ingredients**

Carnauba Wax, Colloidal silion dioxide, croscarmellose sodium, D&C red #27 al lake, dibasic calcium phosphate dihydrate, hypromellose, Lecithin, magnesium stearate, microcrystalline cellulose, polyethylene glycol, Polyvinyl Alcohol, polysorbate, Povidone, Purified water, starch, sodium benozoate, talc, Titanium Dioxide

#### **Questions or Comments**

Call 1-855-314-1850

READ AND KEEP CARTON FOR COMPLETE WARNING AND INFORMATION

#### PACKAGE LABEL.PRINCIPAL DISPLAY PANEL





#### NDC 62011-0316-1

#### **ALLERGY**

diphenhydramine hydrochloride tablet

# Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:62011-0316 Route of Administration ORAL

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

Inactive Ingredients		
Ingredient Name	Strength	
CARNAUBA WAX (UNII: R12CBM0EIZ)		
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		
CROSCARMELLOSE SODIUM (UNII: M28 O L1HH48)		

<b>D&amp;C RED NO. 27</b> (UNII: 2LRS185U6K)	
DIBASIC CALCIUM PHO SPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
PO VIDO NE (UNII: FZ989 GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics			
Color	PINK	Score	no score
Shape	CAPSULE	Size	11mm
Flavor		Imprint Code	EL
Contains			

.	Packaging			
1	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:62011-0316-1	100 in 1 BOTTLE	11/25/2016	
	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	11/25/2016	

### Labeler - Mckesson (177667227)

Revised: 12/2016 Mckesson