

ALLERGY- diphenhydramine hcl tablet

Allegiant Health

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

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:

- sneezing
- runny nose

Warnings

Do not use

- **to make a child sleepy**
- **with any other product containing diphenhydramine, even one used on skin**

Ask a doctor 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 times in 24 hours

adults and children 12 years and over: 1 to 2 caplets

children 6 to under 12 years: 1 caplet

children under 6 years of age: do not use

Inactive Ingredients

croscarmellose sodium, D&C red #27 aluminum lake, hypromellose, lactose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, silicon dioxide, titanium dioxide

Package/Label Principal Display Panel



Diphenhydramine HCl 25mg

ALLERGY

diphenhydramine hcl tablet

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69168-048	
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	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)				
D&C RED NO. 27 (UNII: 2LRS185U6K)				
HYPROMELLOSES (UNII: 3NXW29V3WO)				
LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
Product Characteristics				
Color	PINK	Score	no score	
Shape	CAPSULE	Size	12mm	
Flavor		Imprint Code	AZ048	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69168-048-93	2 in 1 BOX	12/15/2014	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:69168-048-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/15/2014	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL		part341	12/15/2014	

Labeler - Allegiant Health (079501930)

