ALLERGY RELIEF- diphenhydramine hydrochloride tablet, coated Harris Teeter

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.

HTE - 1090 - 2019-1010

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 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

- marked drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- excitability may occur, especially in children
- be careful when driving a motor vehicle or operating machinery

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.

Directions

- take every 4 to 6 hours
- do not exceed 6 doses in 24 hours

adults and children 12 years of age and over	25 mg to 50 mg (1 to 2 tablets)
children 6 to under 12 years of age	12.5 mg * to 25 mg (1 tablet)
children under 6 years of age	ask a doctor

^{* 12.5} mg dosage strength is not available in this package. Do not attempt to break tablets.

Other information

- each tablet contains: calcium 45 mg
- store at room temperature 15°-30°C (59°-86°F)
- retain carton for complete product information

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, D&C red #27, dibasic calcium phosphate, FD&C yellow #6, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, titanium dioxide

PRINCIPAL DISPLAY PANEL

Harris Teeter

Allergy Relief

Compare to the Active Ingredient in Benadryl(R) Allergy Ultratabs(R)

Diphenhydramine HCl, 25 mg

ANTIHISTAMINE

Relieves

Sneezing

Itchy, Watery Eyes

Runny Nose

Itchy Throat





diphenhydramine hydrochloride tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72036-090
Route of Administration	ORAL		

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

Inactive Ingredients	
Ingredient Name	Strength
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)	
D&C RED NO. 27 (UNII: 2LRS 185U6K)	
CALCIUM PHO SPHATE, DIBASIC, ANHYDRO US (UNII: L11K75P92J)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29 V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	

Product Characteristics			
Color	pink	Score	no score
Shape	OVAL	Size	11mm
Flavor		Imprint Code	25;052
Contains			

F	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72036-090- 01	2 in 1 CARTON	08/06/2012	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:72036-090- 05	400 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/27/2012	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	08/06/2012	

Labeler - Harris Teeter (047279351)

Revised: 10/2019 Harris Teeter