ALLERGY RELIEF- diphenhydramine hydrochloride tablet, film coated Spirit Pharmaceutical LLC

Dr. Juan's Santo Remedio

ALLERGY RELIEF

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
 - itchy, watery eyes
 - sneezing
 - itching of the nose or throat
- 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
- trouble urinating due to an enlarged prostate gland
- glaucoma

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 right away. 1(800)222-1222

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 of age and over	1 to 2 tablets
children 6 to under 12 years of age	1 tablet
children under 6 years of age	do not use this product in children under 6 years of age

Other information

- each tablet contains: calcium 24 mg
- store at controlled room temperature 20°-25°C (68°-77°F)
- protect from moisture and light
- see end flap for expiration date and lot number

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, D&C red No 27, dicalcium phosphate, lecithin, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, talc, titanium dioxide

Questions or comments?

1-855-736-3346

PRINCIPAL DISPLAY PANEL

COMPARE TO THE ACTIVE INGREDIENT IN BENADRYL® ULTRATABS®*

Dr. Juan's Santo Remedio

PARA LOS SÍNTOMAS DE LA

ALERGIA

Difenhidramina Antihistamínico Allergy Relief Diphenhydramine

25 MG · 100 TABLETAS/TABLETS



ALLERGY RELIEF

diphenhydramine hydrochloride tablet, film coated

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68210-6112	
Route of Administration	ORAL			
Active Ingredient/Active Moiety				

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40)	DIPHENHYDRAMINE	25 ma

Inactive Ingredients		
Ingredient Name	Strength	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)		
D&C RED NO. 27 (UNII: 2LRS185U6K)		
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)		
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)		
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
TALC (UNII: 7SEV7J4R1U)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		
WATER (UNII: 059QF0KO0R)		

Product Characteristics			
Color	pink	Score	no score
Shape	OVAL	Size	12mm
Flavor		Imprint Code	S4
Contains			

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:68210- 6112-1	1 in 1 CARTON	04/06/2020		
1	100 in 1 BOTTLE; Type 0: Not a Combination Product			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	04/06/2020	

Labeler - Spirit Pharmaceutical LLC (179621011)