ALLERGY RELIEF- diphenhydramine hydrochloride tablet, film coated RETAIL BUSINESS SERVICES, LLC

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.

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?

1-888-333-9792

PRINCIPAL DISPLAY PANEL

Allergy Relief

ALLERGY RELIEF

diphenhydramine hydrochloride tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72476-122
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: M28OL1HH48)				
D&C RED NO. 27 (UNII: 2LRS 185U6K)				
ANHYDRO US DIBASIC CALCIUM PHO SPHATE (UNII: L11K75P92J)				
LECITHIN, SO YBEAN (UNII: 1DI56 QDM62)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)				

POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
WATER (UNII: 059QF0KO0R)	

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

l	Packaging				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
	1 NDC:72476-122-24	2 in 1 CARTON	09/17/2020		
	1	12 in 1 BLISTER PACK; 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	09/17/2020	

Labeler - RET AIL BUSINESS SERVICES, LLC (967989935)

Revised: 9/2020 RETAIL BUSINESS SERVICES, LLC