ALLERGY RELIEF- diphenhydramine hydrochloride tablet, film coated WALGREENS

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.

160R Walgreens 0363 0100 Diphenhydramine Hydrochloride 25 mg tablets

DRUG FACTS

Active ingredient (in each caplet)

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

Ask a doctor before use if you have

- glaucoma
- trouble urinating due to enlarged prostrate gland
- a breathing problem such as emphysema or chronic bronchitis

Do not use

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

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. (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 caplets

children 6 to under 12 years of age: 1 caplet

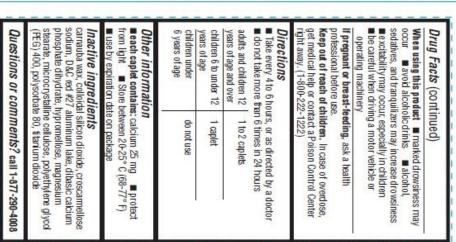
children under 6 years of age: do not use

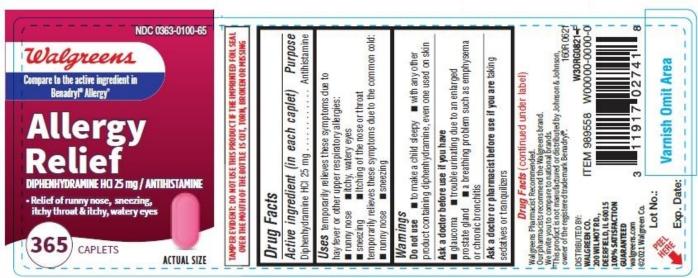
Other information

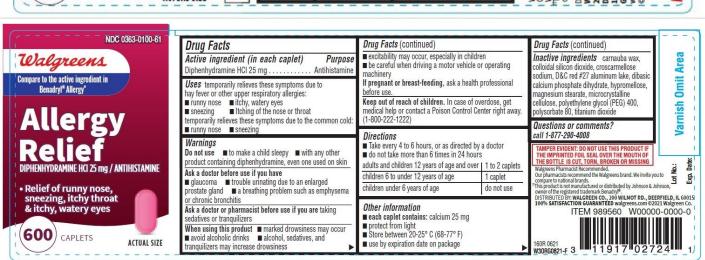
- each caplet contains: calcium 25 mg
- protect from light
- Store between 20-25°C (68-77° F)
- use by expiration date on package

Inactive ingredients carnauba wax, colloidal silicon dioxide, croscarmellose sodium, D&C red #27 aluminum lake, dibasic calcium phosphate dihydrate, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol (PEG) 400, polysorbate 80, titanium dioxide

Adhesive Are







ALLERGY RELIEF

diphenhydramine hydrochloride tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-0100
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		
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)			
CARNAUBA WAX (UNII: R12CBM0EIZ)			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
POLYSORBATE 80 (UNII: 6OZP39ZG8H)			
D&C RED NO. 27 ALUMINUM LAKE (UNII: ZK64F7XSTX)			
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)			
HYPROMELLOSES (UNII: 3NXW29V3WO)			
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)			
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)			

Product Characteristics				
Color	pink	Score	no score	
Shape	CAPSULE	Size	11mm	
Flavor		Imprint Code	T061	
Contains				

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-0100- 65	365 in 1 BOTTLE; Type 0: Not a Combination Product	12/31/2021	
2	NDC:0363-0100- 61	600 in 1 BOTTLE; Type 0: Not a Combination Product	12/31/2021	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	12/31/2021	

Labeler - WALGREENS (008965063)

Registrant - TIME CAP LABORATORIES, INC. (037052099)

Establishment				
Name	Address	ID/FEI	Business Operations	
TIME CAP LABORATORIES, INC.		037052099	manufacture(0363-0100)	

Revised: 12/2021 WALGREENS